FreeStyle Aviator

Insulin Delivery and Glucose Monitoring System

System Kit User's Guide

Abbott

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Welcome

Thank you for selecting the ***FreeStyle Aviator Insulin Delivery and Glucose Monitoring System*** to help you manage your diabetes. **FreeStyle Aviator** is a state-of-the-art continuous insulin delivery and glucose monitoring system designed to make pump therapy easy and safe. This User's Guide has been developed to ensure the ease-of-use, with explanations and guidance that are simple to understand and follow.

Customer Care

Call Customer Care, 24 hours a day, 7 days a week, if you have any questions about the programming or operation of your companion and pump. Abbott Diabetes Care (ADC) Customer Care is staffed with professionals trained to answer your questions. Please have your companion and pump serial numbers available. The serial numbers and the ADC Customer Care telephone number are printed on the back of the companion and pump.

For non-urgent questions, Customer Care can also be reached online at www.AbbottDiabetesCare.com.

- For more information about your blood glucose control or your management of diabetes, call your healthcare professional.
- For questions that involve the mechanics of the pump, call ADC Customer Care.

Learn about the FreeStyle Aviator System

It is very important for you to get to know your new companion and pump before you begin using it.

You should:

➢ Read through this entire User's Guide before using your **Aviator Companion** and **Aviator Pump**.

➢ Work closely with your healthcare professional until you are comfortable with all aspects of pump therapy.

➢ Devote adequate time for record keeping, reading, and meeting with your healthcare professional to ask questions and learn new tips.

WARNING: *The **FreeStyle Aviator Insulin Delivery and Blood Glucose Monitoring System** is intended for continuous delivery of insulin at set and variable rates and as an aid in the management of diabetes mellitus in persons requiring insulin. The **FreeStyle Aviator System** is also intended for the quantitative measurement of glucose in fresh whole capillary blood (in vitro). The system is available by prescription only.*

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Symbols and Important Safety Information

MR	Do not use near MRI	LOT	Lot number
	Read instructions for use	STERILE EO	Sterilized by Ethylene Oxide
Rx Only	For sale by prescription only		Storage Temperature Range
	Type BF Medical Equipment (patient isolated, not defibrillator protected)	CE	CE Mark
IPX8	Water-Tight Equipment (protected against the effects of submersion; tested to 12 feet (3.6 meters) for 24 hours)		Manufacturer
SN	Serial Number		The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries. This product must not be disposed of via general household waste collection. Separate collection for electrical and electronic equipment waste per Directive 2002/96/EC in the European Union is required. Contact the manufacturer for details.
	Expiration date		Do not use if package is damaged
	Do not re-use		Consult instructions for use
REF	Reorder number		

Warnings, Cautions and Important Notes

- **Warnings** – Possible hazards that, if **NOT** avoided, could result in serious injury or death.
- **Cautions –** Hazard that can cause minor personal harm or damage your **Aviator Companion** and **Aviator Pump**.
- **Important Notes –** Important information you need to pay attention to. **NOT** hazard related.

1. Warnings

General

- Read this entire User's Guide before you begin using your **Aviator Companion** and **Aviator Pump**. You should start pump therapy only under the supervision of your healthcare professional. Incorrect usage or failure to follow the instructions provided with the **Freestyle Aviator Insulin Delivery and Glucose Monitoring System** may cause serious injury or death.
- You should always be prepared to inject insulin in case your pump fails or you need to return it for service. If your pump stops and you are **NOT** prepared to give yourself insulin injections, extreme hyperglycemia (high blood glucose) and Diabetic Ketoacidosis (DKA) could develop within a few hours.
- Before going to bed, make sure that the pump contains enough insulin to get you through the night. Failure to do so could result in no insulin delivery and life threatening hyperglycemia.
- The **Aviator Companion** and **Aviator Pump** are **NOT** intended to be used by a person who is hearing-impaired or whose hearing makes it unlikely that the person will hear the companion and pump's sounds.
- The **Aviator Companion** and **Aviator Pump** are **NOT** intended to be used by a person who is visually-impaired or whose sight makes it unlikely that the person will see the companion and pump's screens.
- Ensure that your healthcare professional has oriented you to the size and brightness of the screen.
- The **FreeStyle Aviator System** must only be used with EN60950-1 rated PCs.
- When using the USB features of the system, place the companion in its charger cradle and connect to the cradle's USB port.
- Use **ONLY** ADC supplied cables in order to avoid the risk of electrical shock.
- The graphical output glucose range limitations are 20 to 500 mg/dL (1.1 to 27.8 mmol/L).
- The accuracy of graphical output and statistics are dependent on the time being accurately set.
- Do **NOT** expose your companion or pump to MRI, X-ray, CAT scan, or ultrasound equipment. **ALWAYS** disconnect your companion and pump and store it away from the machines. Do **NOT** bring the companion and/or pump into the procedure room at any time.
- You should have an alternate therapy plan for insulin delivery ready in the event that:
  - ➢ An unexpected interruption in insulin delivery occurs.
  - ➢ The companion and pump do **NOT** operate as described in the system's instructions and guide.

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➢ The companion and/or pump's screen are missing segments or some of the screen is blank. Discontinue use immediately. Use of the system may result in incorrectly displayed information and may cause you to misuse the companion or pump, resulting in possible adverse medical events or serious injury. Call Customer Care and/or your healthcare professional.

- The **Aviator Companion** and **Aviator Pump** are intended only for continuous subcutaneous (under the skin) infusion of insulin and should **NOT** be used for any other type of therapy.
- Discontinue use of the pump and switch to an alternate insulin therapy method in the event that **one or both of the pump's speakers fail to sound** as part of the change from idle mode to basal delivery mode, or following the replacement of a battery.
- It is very important that the time and date are correctly set. Your pump will be programmed to deliver specific basal rates of insulin at specific times of the day. If you set the incorrect time, you may get incorrect insulin amounts, resulting in high or low glucose, and possible adverse medical events including serious injury due to delivery errors.
- If your companion or pump is cracked or a button is torn, this may result in water getting into the internal parts of the pump causing malfunction. Discontinue use and switch to an alternate insulin therapy method immediately **AND** contact your healthcare professional and/or Customer Care. **ONLY** Abbott Diabetes Care should take care of a damaged companion or pump.
- Using your pump and/or companion inappropriately will void the warranty.
- If the pump's status cannot be obtained using the companion, use the pump's screen. If you still cannot obtain the pump status, reposition the companion closer to the pump.
- Do **NOT** use the sterile supplies (reservoir, infusion set, insulin, etc.) after their expiration date. Do **NOT** reuse any disposable supplies.
- Be sure to follow your healthcare professional's instructions for the specific settings described in **Section 6.1 Set Additional Options**.
- Do **NOT** attempt to sterilize your pump.
- Do **NOT** use the pump near flammable or explosive materials.
- Parts of the pump and infusion sets may be a choking hazard. Keep the pump and all accessories out of the reach of small children.
- Discontinue use of the companion's radio link to the pump when on board a commercial aircraft (**Section 6.9**).
- The trainer Mode feature on your pump should only be used for training and should never be used when delivering actual therapy.
- User notification of alarms may be delayed when using Trainer Mode on the pump because notification of Pump alarms is held off whenever the Pump screen is on and displaying a screen other than the Home screen and the Trainer Mode prevents the Pump screen from timing out.
- Although the pump is water resistant, avoid getting it wet because it is **not** waterproof. The pump should **not** be submerged under water or other fluids as this may damage the battery or internal components.

- If your pump has been dropped, the water resistance capability of your pump may be compromised. If you suspect that your pump is damaged, contact your healthcare professional and/or Customer Care.

Insulin Delivery and Calculations

- If you receive an occlusion alarm, you **MUST** disconnect from the pump using the quick disconnect feature of the Infusion Set before investigating the cause of the occlusion. Bolus delivery may occur when the cause of the occlusion is removed. When an occlusion alarm sounds, it is recommended to change the infusion set, tubing, and reservoir.
- Rapid or short-acting U-100 Insulin is the only substance that should be delivered via your pump. Do **NOT** infuse blood, cellular blood products or other medications. Use of any other product may result in adverse medical events or serious injury.
- Ask your healthcare professional which type of insulin you will be using and what action time should be set. If you do **NOT** set these values correctly, you may receive the wrong amount of insulin, which may result in adverse medical events like extreme hyperglycemia and DKA.
- Insulin that has been degraded by environmental conditions (extreme heat over 104ºF (40º C), extreme cold below 30ºF (-1º C), has clots, etc.) may cause adverse medical events or serious injury. Discard any insulin that has been exposed to extreme temperatures.
- Accurate determination and programming of the insulin to blood glucose ratios (insulin sensitivity) are necessary to avoid possible delivery errors that may result in adverse medical events or serious injury.
- Accurate determination and programming of the insulin to carbohydrate ratios are necessary to avoid possible delivery errors that may result in adverse medical events or serious injury.
- Accurate calculation and programming of blood glucose targets and insulin sensitivity are necessary to avoid possible delivery errors that may result in adverse medical events or serious injury.
- The stability of insulin following six days of storage in a pump Reservoir has been verified. Storage of insulin in the Reservoir beyond six days might result in adverse medical events (including serious injury).

Blood Glucose Testing

- Test **ONLY** on your fingers if you are testing for hypoglycemia (low blood glucose) or if you have hypoglycemia unawareness.
- Do **NOT** insert any foreign materials in the test strip port.
- **FreeStyle Lite Test Strips** and lancets are small parts that may be dangerous if swallowed. Refer to package insert for further information.
- Peritoneal dialysis solutions containing icodextrin or compounds of Galactose ≥ 13 mg/dL (≥ 0.7 mmol/L), Maltose ≥ 20 mg/dL (≥0.6 mmol/L) or Lactose ≥ 10 mg/dL (≥ 0.3 mmol/L) cause the integrated **FreeStyle Lite Blood Glucose Meter** to overestimate blood glucose test results. If you are receiving such treatment, do **NOT** use the blood glucose meter and discuss this issue with your healthcare professional to ensure proper treatment.
- Blood glucose levels **MUST** be tested when the pump's operation is stopped. When the pump is stopped, and

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there is **NO** insulin delivered, blood glucose levels will rise resulting in hyperglycemia. Check with your health care professional about instructions for your care when you are disconnected from your pump.

- Always check your blood glucose 1 to 3 hours or as your healthcare professional directs after inserting a new infusion set, refilling the insulin reservoir, or if your pump has stopped operating for any duration. It is imperative that you confirm that insulin is flowing through the pump prior to sleep. Do **NOT** change your infusion set less than 3 hours before bedtime as you need to be awake to notice any problems that may arise with a new site.
- Blood glucose measurements taken outside the companion's operating temperature range may be less accurate.

Reconnecting

- When reconnecting, be sure to check that there is **NO** air in the tubing. If there is air in the tubing, you will **NOT** get the correct insulin dose. Follow the User Guide's recommendations on priming to replace any air in the tubing **before** reconnecting, by using the pump's ***PRIME TUBING*** feature (**Section 2.4**).

Infusion Sets and Reservoirs

- Your pump's reservoir and infusion sets are for **single use only**. Do **NOT** reuse. Use only the **Aviator-**supplied reservoir intended for your pump. Do **NOT** substitute with any other reservoir.
- While the pump and infusion set are disconnected from your body, you can practice filling your insulin reservoir with saline until you are comfortable with the procedure. You **MUST** dispose of the used practice infusion set and reservoir after practicing. Do **NOT** refill the reservoir.
- Before filling the reservoir, make sure your insulin is at room temperature to limit the amount of bubbles. If you have questions about the correct temperature, consult your insulin manufacturer's product insert or your healthcare professional.
- Filling the reservoir with cold insulin may result in delivery errors.
- Do NOT pre-fill and store insulin in the reservoir prior to use in your pump.
- The reservoir protective cover is for temporary use while preparing the reservoir and infusion set for use.
- You must **NOT** have the infusion set tubing connected to your body when removing the reservoir from the pump.
- **ALWAYS** disconnect your pump and infusion set from your body before removing the insulin reservoir from the pump There is a possibility of occurrence of adverse medical events or serious injury if the reservoir is **NOT** installed in the pump and the reservoir is accidentally pressed or hit.
- **NEVER** prime infusion set while attached to your body. If infusion set is attached when priming, this may result in accidental delivery of insulin and possible adverse medical events or serious injury.
- Your pump's reservoir is for **single use only**. Use only the Aviator-supplied reservoir intended for your pump. Do **NOT** substitute any other reservoir. Install the reservoir protective cap to maintain the integrity of the reservoir contents after filling if there is a delay in attaching the reservoir to the infusion set.
- Do **NOT** put the reservoir into the pump without first putting on the reservoir cap.

- Do **NOT** twist the reservoir cap onto the reservoir. Just snap it on and make sure the alignment guides match up.
- Push the reservoir into the reservoir cap until the two are tightly mated to avoid possible delivery errors that may result in adverse medical events (including serious injury).
- Rotate the reservoir cap fully closed when installing the reservoir and infusion set assembly into the Pump to avoid causing delivery errors that might result in adverse medical events (including serious injury).
- Check for any damage to the catch feature before mating the infusion set reservoir cap to the reservoir barrel.
- Do **NOT** hold the plunger while placing the reservoir into the pump.
- Do **NOT** force the reservoir into the pump. Make sure the reservoir alignment mark is lined up with the pump alignment mark and gently wiggle into place.
- Do **NOT** allow any insulin or fluid to get into the reservoir compartment. Use a Q-tip to wipe up the moisture.
- You **MUST** remove all air bubbles, larger than champagne-sized, from your tubing and reservoir. Delivery of air bubbles can result in unexpected hyperglycemia.
- Do **NOT** use an infusion set if the sterile packaging has been damaged.
- Use **ONLY** the **Aviator** infusion sets intended for your pump. **NOT** using the correct infusion set may result in adverse medical events or serious injury.
- You need to install the reservoir in the pump and prime tubing before attaching the infusion set to your body.
- If the infusion set is attached to your body when priming, this may result in accidental delivery of insulin and possible adverse medical events (including serious injury).
- If reservoir, infusion set tubing or cannula is improperly primed, this may result in delivery errors and adverse medical events or serious injury.
- Prime infusion set cannula after every infusion set change.

Basal Rates

- You should **NOT** stop your daily basal delivery program without consulting your healthcare professional. When **NO** basal insulin is being delivered, this can lead to hyperglycemia and DKA. Insulin **MUST BE** delivered by another means. Discuss with your healthcare professional regarding how long you can safely stop your basal rate.
- **STOP** basal delivery before removing the reservoir.
- Accurate basal rate programming and appropriate selection of the active Basal Program are necessary to avoid adverse medical events or serious injury.
- **STOP** basal delivery before removing the battery (**Section 3.1.3**).

Bolus and IOB

- When changing batteries, leaving them out for more than 15 minutes may delete your time and date settings and IOB (Insulin on Board) calculations. Your pump may also lose the history of any recent boluses. Ensure that your pump settings are current after replacing the batteries as described in **Section 6.1**.

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- Appropriate and accurate bolus amounts are necessary to avoid delivery errors that may result in adverse medical events or serious injury. Delivering a meal bolus but then **NOT** eating a meal may result in low blood glucose values. Eating a meal and **NOT** delivering a meal bolus to cover the meal may result in high blood glucose values.

Batteries

- Make sure the fresh battery is at room temperature to avoid false alarms.
- Use **ONLY Duracell MN2400** or **Energizer E92** AAA alkaline primary battery (non-rechargeable) in your pump.
- Do **NOT** use lithium, nickel cadmium (NiCad), nickel metal hydride (NiHM), carbon zinc (heavy duty), or rechargeable batteries in your pump. Using other types of batteries may shorten the life of the battery, cause inappropriate low battery alert warnings, or fail to give low battery alert warnings.
- The **Aviator Companion** contains lithium internal batteries.
- At the end of their useful life dispose of **FreeStyle Aviator System** components and accessories according to local environment and other rules and regulations that may apply.

Alarms

- If you receive an occlusion alarm, you **MUST** disconnect from the pump using the quick disconnect feature of the Infusion Set before investigating the cause of the occlusion. Bolus delivery may occur when the cause of the occlusion is removed.
- Continued use of a pump with malfunctioning sounds may result in the user being unaware of an alarm or alert condition or that delivery has stopped, resulting in possible adverse medical events or serious injury.
- When your insulin supply is low, there will be a Low Insulin Alert or No Insulin alarm. Also, the insulin icon in the **Levels** panel on the **Home** screen will show the level of insulin in the reservoir.

2. Cautions

General

- Remove your pump before prolonged exposure to water, and follow your healthcare professional's recommendations on insulin dosing when you are disconnected from the pump.
- You should avoid exposing your pump to temperatures above 104º F (40º C), common in hot tubs, whirlpools, and saunas.
- If your pump is exposed to extreme temperature ranges (see **Section 10**), there is a possibility the insulin in your pump will be damaged or destroyed. The insulin in the reservoir and tubing needs to be replaced (see **Section 2.4**), and the infusion set changed.
- If the **Aviator Pump** is carried at a vertically higher position than the infusion site, a very small amount of additional insulin infusion or interruption delivery may take place. To minimize this condition and maintain pump delivery accuracy, the pump should be carried no higher than 12 inches (30 cm) above the insertion site. For those using basal rates of less than 1.0 units per hour, this may be especially important. When using very low basal rates of less than 1.0 units per hour, position the pump vertically below the level of the infusion site to eliminate this condition. This behavior is common to most traditional insulin pumps.
- If Aviator Pump is exposed to large changes in vertical height, a small amount of additional insulin infusion or interruption of delivery may take place. To minimize this condition and maintain pump delivery accuracy, avoid sudden large changes in height between the pump and infusion site, when using basal rates less than 1.0 unit per hour. This behavior is common to most traditional insulin pumps.
- If the pump malfunctions or a problem is detected, the pump will alarm. If you **CANNOT** resolve the alarm and the issue continues, contact Customer Care.
- If **Aviator Pump** is exposed to large temperature changes, a small amount of additional insulin infusion or interruption of delivery may take place due to thermal expansion or contraction of the insulin volume. This behavior is common to most traditional insulin pumps. To minimize this condition and maintain pump delivery accuracy, avoid large temperature changes The resulting insulin delivery or interruption in delivery more greatly affects people who use basal rates less than 1.0 units per hour.
- If **Aviator Pump** is exposed to a high G force, such as might occur on an amusement park ride, it might cause a small volume of insulin to be either unintentionally delivered to your body, or unintentionally be siphoned from your body.
- Be careful **NOT** to use too much force to place the battery cap on the pump. Excess force can lead to bending or breaking of the metal prongs.
- The **Aviator Pump** is intended for your own personal use only. Do **NOT** share your pump with others.
- Make sure the hub connections are properly tightened. If any are loose, insulin may accidentally leak out of the system, reducing insulin delivery, and your blood glucose levels could rise rapidly to dangerous levels.
- Hyperbaric chambers will affect pump operation and may damage the pump.
- Avoid high humidity (greater than 90 percent) and high or low (10,000 feet [3048 meters] or more above sea

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level) atmospheric pressure, as the system may not operate properly under those conditions.

- Do **NOT** use household or jewelry cleaners, petroleum-based products, or products containing high levels of N, N-diethyl-m-toluamide (DEET) near the pump as they may damage the pump's case. Also be sure that your hands are free of these products before touching the pump.
- Do **NOT** use abrasive cleaners or sharp instruments while cleaning your pump, as they may damage the case or screen, a damaged case or screen will **NOT** be water-resistant, and will require service. Small cracks resulting from sharp objects can allow water from the atmosphere to damage pump internal parts.
- Do **NOT** use steam or hot water to clean your pump.
- Do **NOT** put your pump in the dishwasher or microwave.
- Do **NOT** use a hairdryer to dry your pump.
- Be sure to review with your healthcare professional any changes in your daily routine as well as strategies for daylight savings time and travel across time zones.
- The **Aviator Pump** is designed for use with the parts and accessories recommended in the User's Guide. Use with other manufacturer's parts and accessories may result in inaccuracies or damage the pump.
- If your companion or pump is damaged, it will need to be serviced or replaced. Call Customer Care to obtain detailed instructions regarding servicing or replacement procedures.
- The **Aviator Pump** should be visually checked often when surrounding noise levels make it unlikely that the pump's sounds can be heard.
- Do **NOT** create a Food Event entry on the companion to cover food for which you created a Food Bolus event, as the system will log Carbs entered through a Food Bolus event.
- To reduce the possibility of spreading an infectious disease, caregivers should take proper cautions, such as wearing gloves, when handling components of the **FreeStyle Aviator System** that is used by another person.
- Results from **FreeStyle Control Solution** tests do **NOT** reflect your blood glucose level.

Insulin Delivery and Calculations

- **WHILE AN ALARM IS ACTIVE**, **INSULIN DELIVERY IS STOPPED**. Therefore, it is important for you to respond to an alarm as soon as possible.
- Insulin delivery does **NOT** stop with **ALERT**. However, delivery is **NOT** occurring when you get a Pump Idle Alert, because you have **NOT** begun insulin delivery yet.

Blood Glucose Testing

- Follow your healthcare professional's recommendations for checking your blood sugar when you have been off the pump. To prevent high glucose, follow your healthcare professional's recommendations for replacing missed basal and bolus insulin when you are disconnected from the pump.

Infusion Sets and Reservoirs

- You **MUST** replace the pump's reservoir and infusion set each time you replenish your insulin supply.

- You **MUST** change your infusion set every three days or sooner according to your healthcare professional's advice. You may need to change your infusion set more frequently if it becomes dislodged, if skin irritation or signs of infection develop, signs of poor control appear, or at the advice of your healthcare professional.
- You must replace your infusion set every time you change your pump's reservoir and vice versa.
- Use aseptic techniques when filling the reservoir and connecting the infusion set. Make sure everything is clean and sterile to prevent infection.

Basal Rates/Bolus

- When setting a temporary basal percent, make sure that you are setting the percent of your basal that will be delivered and **NOT** the percentage reduction in your basal rate. Refer to **Section 6.1**.

3. Important Notes

General

- Follow all instructions provided with your pump's accessories (infusion sets, etc.).
- The User's Guide contains **NO** specific recommendations regarding the treatment of your diabetes. You should work with your healthcare professional to design the best treatment program for your specific needs.
- Regular medical checkups are an important part of pump therapy. Your healthcare professional plays a key role in your diabetes management.
- Work with your healthcare professional to learn how to use the **FreeStyle Aviator System**. Consult your healthcare professional when any problems or questions arise.
- Work with your healthcare professional to obtain proper instruction on how to program and deliver boluses, and how to use basal programs to enhance your use of the **Aviator Pump**.
- Talk with your healthcare professional about your individual insulin needs.
- Ask your healthcare professional to help you complete the Table of Settings in **Section 11 – Appendix A**, to meet your personal needs.
- You should consult your healthcare professional before making any major edits or changes to your basal program(s).
- You will hear a number of clicks depending on your movements on the scroll pad. Be sure to always check that you have scrolled to the correct menu or option as desired.
- Before you go to sleep, be sure the tubing is **NOT** where pets or children might pull or chew on it. Keep tubing close so it will **NOT** dislodge the infusion set.
- Protection against delivery errors is provided by two microprocessors, which continuously check each other. In addition, two position sensors in the pump's drive mechanism are regularly cross checked to protect against errors caused by sensor or drive mechanism malfunction.

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- Electromagnetic interference (EMI) sources, such as radio and TV station transmitters, amateur radio (HAM) transmitters, two way radios and cellular phones can affect the delivery of insulin in battery powered insulin delivery devices. Follow the warnings listed below to reduce the chance of user interface distortion or the stoppage of an insulin delivery of your **FreeStyle Aviator System**, which could result in adverse events or serious injury:
  - ➢ Do **NOT** use your **FreeStyle Aviator System** during MRI; leave your **FreeStyle Aviator System** outside the MRI procedure room.
  - ➢ Be aware of nearby transmitters, such as radio and TV towers, and avoid going close to them.
  - ➢ Do **NOT** place your **FreeStyle Aviator System** next to another electronic device such as a cellular phone.
  - ➢ Be aware that adding accessories or modifying the **FreeStyle Aviator System** may make it MORE susceptible to interference from EMI (Refer to **Section 12D** for more information).

Blood Glucose Testing

- Check your blood glucose level frequently as recommended by your healthcare professional and follow recommendations from your healthcare professional when your blood glucose is too high or too low.
- To ensure accurate results, wash your hands and test site (for example, your forearm) with soap and water. Make sure there is **NO** cream or lotion on the test site. Thoroughly dry your hands and test site.
- Use **ONLY** the **FreeStyle Lite Test Strips** with the companion. Using other test strips will produce inaccurate results.
- For important test strip information, including detailed storage and usage information, refer to the **FreeStyle Lite Test Strip** package insert.
- Do **NOT** reuse lancets. Use a new sterile lancet for each test. **NEVER** use a lancet or lancing device for more than one person.
- It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another site or adjust lancing depth.
- Do **NOT** use test strips more than once. Discard used test strips in accordance with local disposal regulations.
- Do **NOT** press the test strip against the test site.
- Do **NOT** scrape the blood onto the test strip.
- Do **NOT** apply blood to the flat side of the test strip.
- Do **NOT** apply blood to the test strip when the test strip is out of the companion.
- Do **NOT** apply blood to both edges of the test strip.
- Do **NOT** put blood or foreign objects into the companion's test strip port.
- Low or high glucose readings can indicate a potentially serious medical condition. LO readings display as less than 20 mg/dL (1.1 mmol/L), and HI readings display as over 500 mg/dL (27.8 mmol/L).
- Use a sealed container such as a Sharps container to avoid exposure to the sharps by yourself or someone else.

Your community requires safe disposal of sharps.

- **FreeStyle Control Solution** is good for three months after opening the bottle or until the expiry date printed on the label, whichever comes first.
- Count forward three months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle.
- The control solution range is a target range for control solution only. It is **NOT** a target range for your blood glucose level.

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1 Getting Acquainted

1.1 How to Use this Guide

Purpose	To learn to use this User's Guide so you can find the information you need to use your **Aviator Companion** and **Aviator Pump** correctly and safely.
When	Do this task: • **Before you use your Aviator Companion and Aviator Pump for the first time.** • When you are ready to begin reading the User's Guide.
Materials	• The ***FreeStyle Aviator System User's Guide***.

Helpful Information

- It is very important for you to get to know your new companion and pump before you begin using it. You should:
  - ➢ Read through this entire User's Guide before using the companion and pump.
  - ➢ Work closely with your healthcare professional until you are comfortable with all aspects of pump therapy.
  - ➢ Devote adequate time for record keeping, reading, and meeting with your healthcare professional to ask questions and learn new tips.
- Don't be afraid to ask questions. Keep a list of the questions you have as you progress through the User's Guide and as you begin wearing your pump. The list will help you remember to ask questions at your follow-up visit with your healthcare professional.

How to Use this Guide

This User's Guide provides the information you need to use your new companion and pump. Information is divided into sections. Most tasks can be performed using the companion or the pump, or either one. This User's Guide provides instructions for using the Aviator Companion to operate the system, call Customer Care if you need instructions on operating the pump only.

Each section contains useful information about:

- Purpose of the task.
- When to do the task.
- Materials you will need to perform the task.
- Helpful information such as important notes or tips.
- Steps you need to follow to complete the task.

As you complete each section of the User's Guide:

- Read through the section and complete each task, following the outlined steps. Be sure to check your work.
- Explore and move around in **FreeStyle Aviator's** menus and screens.
- Pay particular attention to the ***Warnings, Cautions***, and ***Notes*** highlighted in the boxes. They provide key safety information that will help you use the **Aviator Companion** and **Aviator Pump** safely.
- Complete each task and check your work at the end as appropriate.
- Refer to the **Glossary** if you need the definition and information about a specific term. Key terms will be in **blue**.
- Refer to the **Table of Contents** if you need information about a specific topic.

What to Ask Your Healthcare Professional

About Using the Companion and Pump

- What should I do if I have problems operating the companion and/or pump as described in the User's Guide?
- What back-up insulin therapy method should I use if the pump fails to operate as described in the User's Guide?
- What are my personal settings for the **Table of Settings** in **Section 12 - Appendix A**?

Other Questions to Consider

- When should I contact my healthcare professional with questions?
- What other resources does my healthcare professional recommend?

Key Terms

Key terms in each section will be in **blue**. Refer to the **Glossary** (in the back of the **User Guide**) for definitions and information about any specific term.

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1.2 Identify Parts of the System

Purpose	To identify and locate parts of the system and get familiar with the system so you can use your **Aviator Companion** and **Aviator Pump** safely and correctly.
When	Do this task: • **Before you use your Aviator Companion and Aviator Pump for the first time.** • Before you program your pump for use.
Materials	• The ***FreeStyle Aviator System User's Guide*** (This document). • Your **Aviator Companion** (The remote handheld used to operate pump). • Your **Aviator Pump** (The insulin delivery pump).

Helpful Information

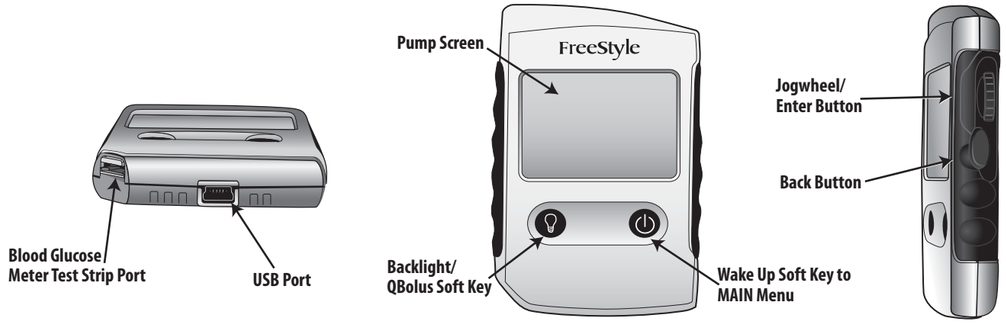
FreeStyle Aviator Insulin Delivery and Glucose Monitoring System continuously delivers **insulin** to your body in a way that closely matches how the body delivers insulin throughout the day. By using information you and your healthcare professional develop together and programming your doses accurately into your **Aviator Pump**, your pump is able to do two important things:

1. Every few minutes, it will provide your body with **basal insulin**. Basal insulin is the continuous trickle of insulin necessary to suppress glucose production by your body in between meals and overnight. Basal insulin is personalized to your specific needs and then spread out over a 24-hour period.
2. At specific times, you will program the pump to deliver a **bolus** of insulin. Bolus insulin is an extra burst of insulin taken either to cover the rise in **blood glucose** that occurs after eating, or to correct high blood glucose.

Caution: *To reduce the possibility of spreading an infectious disease, caregivers should take proper cautions, such as wearing gloves, when handling components of the* ***FreeStyle Aviator System*** *that is used by another person.*

Identify Parts of the Aviator Companion

This section introduces you to the parts of your new **Aviator Companion**. Place your companion next to the picture below and locate the parts of the companion.



Note: *Your* ***Aviator Companion*** *is designed to always be ON when the batteries are charged.*

Companion Parts

- **Back Button** – The oval shaped lower button on the right side of the companion screen below the jogwheel. It is used to cancel a change made to a value, and to move back to the previous screen.
- **Backlight/QBolus Soft Key** – To turn on/off the backlight, press the bottom left soft key on the companion with the light bulb icon for 2 seconds when you are **NOT** at the **Home** screen. To deliver a quick bolus, press the **QBolus** soft key from the **Home** screen. Using the jogwheel, select amount of bolus to deliver and press **Enter** button.
- **Blood Glucose Meter Test Strip Port** – The port where you insert a test strip when checking your blood glucose.
- **Companion Screen** – The part of the companion where the information is displayed.
- **Jogwheel/Enter Button** – The top jogwheel button on the right side of the companion. It scrolls to allow you to move up and down through the companion options. You can also use this button to select an item and to move forward to the next screen. You can also stop a bolus in progress.
- **Wake Up Soft Key to MAIN MENU** – To wake up the companion, press the bottom right soft key with the Power icon for 2 seconds to access the **MAIN MENU**.
- **USB Port** – The USB port to connect to the charger of your companion's battery.

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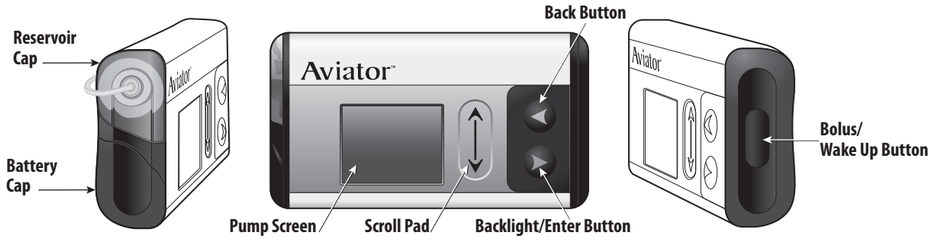
Identify Parts of the Aviator Pump

This section introduces you to the parts of your **Aviator Pump**. Place your pump next to the picture below and identify the parts of the pump.

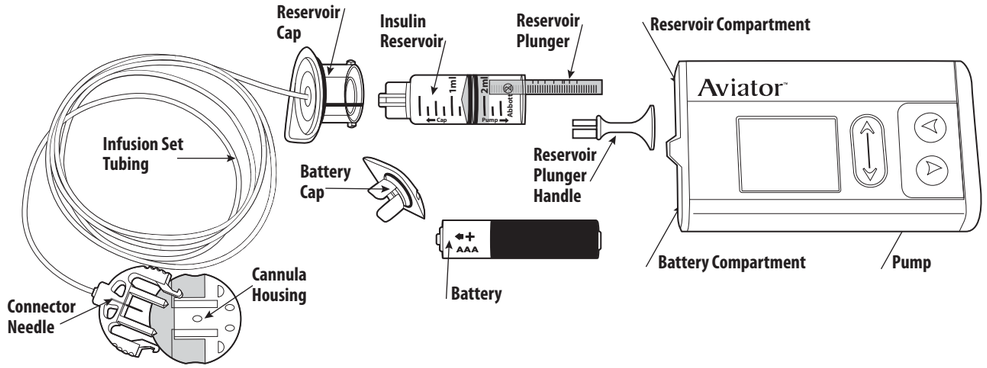


Note: *Your **Aviator Pump** does **NOT** have an on/off button. Your pump is designed to always be on when the batteries are in. The screen may go blank when it times out.*

Pump Parts

- **Back Button** – The top button on the right side of the **pump screen** with an indented triangle pointing to the left. It is used to cancel a change made to a value, or to move back to the previous screen.
- **Backlight/Enter Button** –The bottom button on the right side of the pump screen with an indented triangle pointing to the right .To turn on/off the backlight, press this button for 2 seconds. It is also used to select an item and to move forward to the next screen.
- **Display Right or Left –** A setting that allows you to switch the screen orientation such that the buttons are on the right side of the pump for right-handers or on the left side of the pump for left-handers.
- **Battery Cap** – Cap cover for the battery compartment.
- **Battery Compartment** – Where the pump battery is stored.
- **Bolus Button/Wake up Button** – The button on the side of the pump. Press it the number of times needed to deliver a quick bolus using the **One-Button Bolus** function. You can also press it once to stop a **bolus** in progress. Press and hold the button to wake up the pump from **sleep mode**, and see the **Home** screen.
- **Pump Screen** – The part of the pump where the information is displayed.
- **Scroll Pad** – The indented, oval area on the right side of the pump screen. It scrolls to allow you to move up and down through the pump options. It is like the scroll pad on a computer.

The picture below identifies the parts of the Insulin Reservoir.



Insulin Reservoir Parts

- **Insulin Reservoir** – Located on the upper-left side of your pump. The reservoir holds the insulin your pump will deliver to your body. The reservoir holds 250 **units** of insulin. Your healthcare professional will tell you how much insulin to use when you fill the reservoir. The reservoir is a single-use only item. Discard it after a single use. Multiple uses of the reservoir may result in problems with insulin delivery.
- **Dust Cover** – The cover that comes with your pump used to protect the reservoir compartment (**NOT** pictured).
- **Reservoir Cap** – The clear plastic cap and handle that is on the outside of your pump when the reservoir is placed in the pump. This connects the Reservoir to the infusion set.
- **Reservoir Compartment** – The hollow area in the pump that houses the insulin reservoir.
- **Reservoir Plunger** – The gray plunger of the insulin reservoir.
- **Reservoir Plunger Handle** – The handle attached to the end of the plunger that is removable. Used only to draw insulin into the reservoir, and is discarded after the reservoir is filled.

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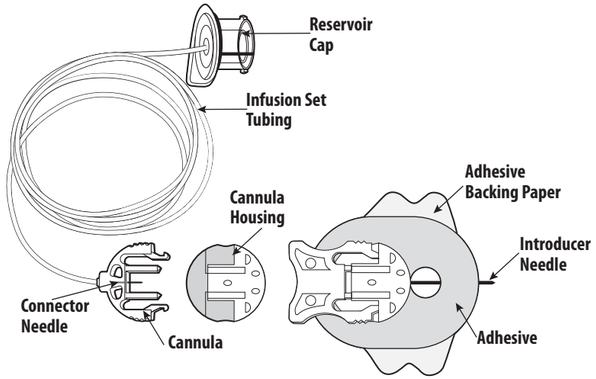
The picture below identifies parts of the infusion set.



Infusion Set Parts

- **Cannula** – A slender plastic tube that is under the skin and delivers the insulin in your body. During the insertion of the infusion set, the center of the cannula contains a fine gauge introducer needle to help the cannula penetrate the skin. The introducer needle is then removed after insertion, leaving the plastic cannula in your skin.
- **Cannula Housing** – The part of the infusion set where the tubing connects to the infusion set on your body.
- **Connector Needle** – The part of the infusion set that contains a needle to connect to the cannula.
- **Infusion Set** – The combination of the reservoir cap, tubing, and cannula that delivers insulin from the pump's reservoir into your body. It is used one time only, and is discarded after each use.
- **Infusion Set Tubing** – Part of the infusion set that carries insulin from the pump to the cannula.
- **Introducer Needle** – The needle inside the cannula that helps insert it under your skin. The needle is removed and only the cannula is left in your body.
- **Reservoir Cap** – The clear plastic cap and handle that is on the outside of your pump when the reservoir is placed properly in the pump. This connects the Reservoir to the infusion set.

Getting Familiar with the System

You will be using the jogwheel, buttons, and soft keys to move around the menus and screens of your **Aviator Companion** after it is charged and set up. Review how you will be navigating the system:

Jogwheel / Button / Soft Keys	Use this to	Activate this by
Jogwheel	• Scroll through and highlight panels, menus, or screen options that you want to select.	Scrolling the jogwheel using either your thumb or index finger in an upward or downward direction. ***Important Note:*** Be sure to always check that you have scrolled to the correct menu or option as desired.
Enter button	• Select and highlight actions such as **Clear**, **OK**, **Done**, **Skip**, **Edit, Yes**, or **No**, to advance to the next screen. • Confirm the panel, menu, screen options, and actions that you have highlighted and selected. • Move forward to the next screen. • Stop a normal bolus in progress.	Pressing the jogwheel on the right side of the companion.
Back button	• Go back to the previous menu or screen. • Cancel a value that was changed.	Pressing the oval shaped **Back** button on the right side of the companion screen below the jogwheel.
Backlight/QBolus soft key	• Turn on/off the backlight.	Pressing the bottom left soft key on the companion that has a light bulb icon for 2 seconds, when you are **NOT** at the **Home** screen.
	• Deliver a quick bolus.	Pressing the **QBolus** soft key from the **Home** screen. Using the jogwheel, select amount of bolus to deliver and press **Enter** button.

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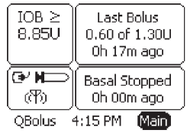
Jogwheel / Button / Soft Keys	Use this to	Activate this by
Wake Up soft key	• Wake up the companion from **low power sleep state**. ***Note:*** *The **Home** screen appears with **Main** highlighted whenever you wake up the companion.* • Access the **MAIN MENU** from the **Home screen**.	Pressing the bottom right soft key with the Power icon for 2 seconds until ***Main*** is highlighted.

Note: *You can activate the **Sleep** mode to quiet an **alert** for as little as 15 minutes or as long as 12 hours. It is like hitting a snooze button on an alarm clock. For example, if **Sleep** is highlighted and you want to change it to 1 hour, then press **Enter**, scroll to 1 hour, and press **Enter** again.*

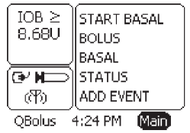
Note: *You may also want to set your timeout to longer than 15 or 30 seconds initially as you practice using your companion and setting up all your basic options. Refer to **Section 6.1** and ask your healthcare professional for help as needed.*

The **Home** screen will appear after initial set-up is complete, and when you wake up your companion from low power sleep state. There are two options for setting up the **Home** screen:

- **Information** based (displays **basal** and bolus insulin delivery status information)



- **Activity** based (displays a list of menu items such as Alarms, Status, Reports, Setup, etc.)



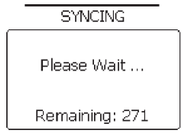
You will go to the **Home** screen when you need to:

- View basal and bolus insulin delivery status information (Information-based **Home** screen only).
- View insulin reservoir level (The syringe icon in the **Levels panel** on the bottom left indicates the reservoir's insulin level.
- View battery level (The battery icon in the Levels panel on the bottom left indicates the pump's battery level.
- View RF signal (Radio Frequency signal On/Off – indicates whether the companion and pump are connected or not)
- Access all other companion functions, menus, and screen options.

Other Tips

- You may get **CONFIRMATION** screens and messages that require your decision on specific actions. Always check that you are selecting the correct actions to take as you perform tasks on your pump.
- You may have to **Clear** alerts/alarms or **Skip** certain options/actions. Make sure you select the correct actions to take.
- When you receive a **Pump Idle alert**, you can select **Clear** the alert to return to the **Home** screen. You will also have the option to put your pump to sleep for 15 minutes (default), or program your pump to **Sleep** for longer than 15 minutes to quiet an alert, until you are ready to **prime** your pump later.
- You must highlight and select **Done** and press **Enter** button for all setting changes to be saved to your system.
- You can press **Enter** on items that are set to dashes, e.g., time.
- The **WARNING** screen with "Dashed items must be set." message displays if you try to press the **Enter** button in a screen where **Next**, **Done**, or **Accept** is selected, when you have **NOT** completed all required information. You will notice that **OK** is highlighted and you will need to press the **Enter** button. Complete all information as required.

- You may see dashes displayed for status information on the companion's **Home** screen until connection is established and status information is obtained from the pump.
- You will see a "**SYNCING**" screen when you access pump menus (**BASAL/BOLUS/SETUP**) from your companion.
- When accessing **PUMP DIARY** or **BOLUS HISTORY** from your companion, you may see the "**SYNCING**" screen for a longer period.



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1.3 Charge Companion Battery

Purpose	To fully charge the companion's battery so that you can use it to operate the pump.
When	Do this procedure: • Before you set up your companion and pump for the first time. • Anytime you see the **Low Battery Alert** screen.
Materials	• Your **Aviator Companion**. • Companion charger cradle.

Helpful Information

- Your companion will also be charged if connected to a powered USB cable.

WARNING: *Use **ONLY** the USB cable provided. Use of an unapproved cable may lead to loss of electromagnetic compatibility, and make the system more susceptible to electronic interference.*

Procedure:

Steps	Do This
1. Connect companion to charger.	**a.** Connect your charger cradle to an electrical outlet. **b.** Place your companion into the cradle. **c.** Charge your companion's battery for at least **6 hours**.
2. Allow your companion to fully charge. --- : --- ---	Notice battery is charging.
3. Check your work. 2:18 PM	Notice that your battery is fully charged.

1.4 Install Pump Battery

Purpose	To install or replace your pump battery.
When	Do this procedure: • Before you set up your pump for the first time. • Anytime you see the Low Battery Alert screen.
Materials	• One **Duracell MN2400** or **Energizer E92** AAA alkaline primary battery (non-rechargeable).

Warning: *Do **NOT** use any other battery including lithium, nickel cadmium (NiCad), nickel metal hydride (NiHM), carbon zinc (heavy duty), or rechargeable batteries. Using other types of batteries may shorten the life of the battery, cause inappropriate low battery alert warnings, or fail to give low battery alert warnings.*

Helpful Information

- Once the battery is installed correctly, you will hear a series of beeps and vibrations confirming that the pump's speakers and vibrating device are working properly.
- Your battery will typically last at least four weeks. Battery life may be shortened if you select the vibrate setting instead of the audio setting, or use the backlight frequently. The number of **alarm**s/alerts you receive will also impact battery life.
- **Always** carry a spare battery with your pump supplies.
- Remove the battery if you are storing your pump for prolonged periods of time.
- Do **NOT** remove an existing battery unless you are storing your pump for a long period of time. Removing the battery for a long period of time could result in losing some settings and then having to reset them.
- Do **NOT** use a cold battery (e.g., one that has just been in your refrigerator or in your car in cold weather). If the battery is cold, the pump may display a battery-related **alarm** as the pump may **NOT** be receiving full power. The battery level display may be inaccurate.
- Expended batteries should be disposed of in accordance with local regulations.

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Procedure:

Steps	Do This

1. Prepare to install a new battery into your pump.

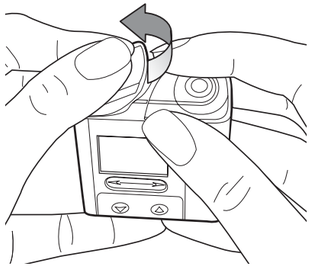
If you are	Then do this
Already wearing the pump	1. **Stop basal** delivery. See Section 3.1.1 for procedure. 2. Disconnect your pump and infusion set from your body. Follow the procedure described in your infusion set's instructions to disconnect the infusion set. ***Note:*** *You may only need to detach the cannula from the cannula housing.* 3. Go to Step 2.
Setting up the pump for the first time	Go to Step 2.

2. Obtain a fresh AAA alkaline battery.

Be ready to install a fresh battery within 15 minutes of removing the old battery.

Warning: *A 15 minute delay may delete your time and date settings and* ***Insulin on Board (IOB)*** *calculations. Your pump may also lose the history of any recent boluses. Make sure the fresh battery is at room temperature to avoid false alarms.*

3. Remove the battery compartment cap.



a. Find the battery compartment on the side of your pump.

b. With the pump screen facing you, as shown in the picture, place your thumb on the groove and turn the cap counter-clockwise until the cap pops out.

c. If necessary, gently pull the battery cap off.

d. Decide what to do next.

If you are	Then do this
Removing an old battery	Go to Step **4**.
Installing a fresh battery	Go to Step **5**.

Steps	Do This

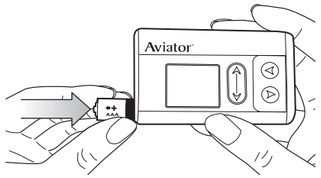
4. Remove the battery.

If necessary, tap the pump against your hand or gently pull to remove the battery.

The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

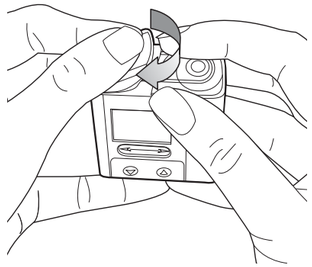
5. Insert a fresh battery.

Insert the battery *negative end* (-) first.



6. Replace the battery component cap.

a. Carefully place the metal prongs of the battery cap into the space between the battery and the inside of the pump compartment at a 90 degree angle.



b. Push down and use your thumb to press the cap in place.

c. Twist cap clockwise to close it securely.

Caution: *Be careful* ***NOT*** *to use too much force to place the battery cap on the pump. Excess force can lead to bending or breaking of the metal prongs.*

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Steps	Do This
7. Check your work.	***Caution:*** • *All the signals below must be presented. If any signals below do **NOT** occur, reinsert the battery again or try inserting another fresh battery.* • *If the problem happens again, do **NOT** use the pump. Switch to an alternate insulin delivery method and call your healthcare professional or Customer Care.* **a.** Notice the **Power up** screen will appear. **b.** Listen for one long beep and four quick beeps. **c.** Feel two short vibrations. **d.** Look for the next screen.

If you are	Then do this
Setting up the pump for the first time	You will see the **Set Date/Time** screen. STEP 1 Set language, time, date, insulin, alarm. OK Go to **Section 2.2** to Set Up Your System.
Replacing the battery within 15 minutes after the pump has already been initialized	1. You will see the **TIME/DATE** screen. TIME/DATE 1:10 PM Jan 01, 2008 Next Format 2. Notice **Next** is highlighted. 3. Press **Enter** button to return to **Home** screen. 4. Reconnect cannula to cannula housing and then **RESTART** your basal delivery from your companion.

2 Using the System for the First Time – Quick Setup

2.1 Set Up Your System

Purpose	To program basic information into your **Aviator Pump** including time and date, insulin profile, and **inactivity alarm**, using your **Aviator Companion**.
When	Do this procedure: • After you have charged the companion's battery, and installed the pump's battery. • Before you use your companion and pump as a system for the first time.
Materials	• Your companion fully charged and powered on. • Your pump with battery installed. • Your companion and pump already paired. This means that your pump is associated with your companion and your pump and companion can only communicate with each other. • Information from your healthcare professional about the type of insulin you will use with your pump and other setting information that you will need as recorded in your Table of Settings in **Section 12** – **Appendix A**.

Helpful Information

- You will perform this task using your companion, and the settings will automatically be set up on your pump as well.
- Before entering your settings, be sure to ask your healthcare professional which type of insulin you will be using and what is the length of its action time. Record your personalized settings in the Table of Settings in **Section 12** – **Appendix A**.
- When you have more experience with pumping, you can set up your companion with more optional settings in **Section 6**.
- If you are interrupted while doing this setup, the pump will beep to let you know it is waiting for you to finish these steps.
- For a detailed list of the screen settings and the order in which they appear, refer to the **Freestyle Aviator Menus** in **Section 12 – Appendix G**.

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Procedure (First Time Initial Setup):

Steps	Do This
1. Set time and date using your FreeStyle Companion. TIME/DATE --- : --- --- --- ---, --- Accept	***WARNING:*** • ***It is very important that the time and date are correctly set.*** *Your pump will be programmed to deliver specific* ***basal rates*** *of insulin at specific times of the day. If you set the incorrect time, you may get incorrect insulin amounts, resulting in high or low glucose, and possible adverse medical events including serious injury due to delivery errors.* ***Caution:*** • *Be sure to review with your healthcare professional any changes in your daily routine as well as strategies for daylight savings time and travel across time zones.* **a.** Notice **Time** line with dashes is highlighted. **b.** Press **Enter** button.
2. Set current hour. SET TIME Hour = --- Minute = --- AM/PM = AM Accept SET TIME Hour = 02 Minute = --- AM/PM = AM Accept	**a.** Notice **Hour** is highlighted. **b.** Press **Enter** button. **c.** Scroll to the current hour. **d.** Press **Enter** button.

Steps	Do This
3. Set current minutes. SET TIME Hour = 02 Minute = --- AM/PM = AM Accept SET TIME Hour = 02 Minute = 11 AM/PM = AM Accept	**a.** Notice **Minute** is highlighted. **b.** Press **Enter** button. **c.** Scroll to the current minutes. **d.** Press **Enter** button.
4. Set AM or PM. SET TIME Hour = 02 Minute = 11 AM/PM = AM Accept SET TIME Hour = 02 Minute = 11 AM/PM = PM Accept	**a.** Notice **AM/PM** is highlighted. **b.** Press **Enter** button. **c.** Scroll to select **AM** or **PM**. **d.** Press **Enter** button.

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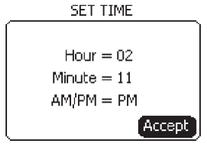
Steps / Do This

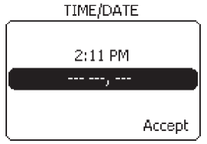
5. Check your time settings.



Check that you have set the correct time.

If settings are	Then do this
Correct	Notice **Accept** is highlighted. Press **Enter** button.
Incorrect	1. Scroll up to highlight the item you want to change. 2. Press **Enter** button. 3. Scroll to the correct setting. 4. Press **Enter** button. 5. Scroll to highlight **Accept**, if not already highlighted. 6. Press **Enter** button.

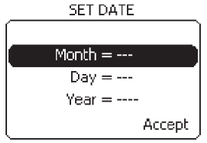
6. Set date.



a. Notice the date line with dashes is highlighted.

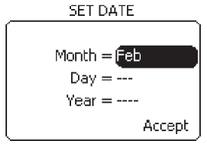
b. Press **Enter** button.

7. Set current month.



a. Notice **Month** is highlighted.

b. Press **Enter** button.

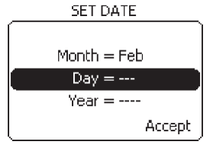


c. Scroll to the current month.

d. Press **Enter** button.

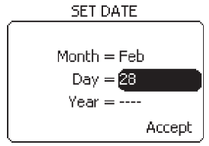
Steps / Do This

8. Set current day.



a. Notice **Day** is highlighted.

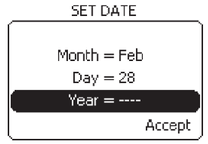
b. Press **Enter** button.



c. Scroll to the current day.

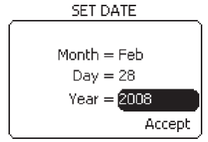
d. Press **Enter** button.

9. Set current year.



a. Notice **Year** is highlighted.

b. Press **Enter** button.



c. Scroll to the current year.

d. Press **Enter** button.

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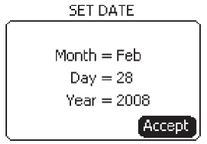
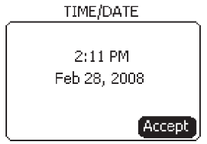
2/9/09 11:29:34 AM

Steps	Do This
10. Check your date settings.	Check that you have set the correct date.



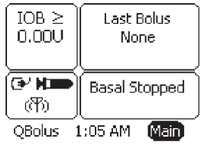
If settings are	Then do this
Correct	Notice **Accept** is highlighted. Press **Enter** button.
Incorrect	1. Scroll up to highlight the item you want to change. 2. Press **Enter** button. 3. Scroll to the correct setting. 4. Press **Enter** button. 5. Scroll to highlight **Accept**, if not already highlighted. 6. Press **Enter** button.

11. Verify your Time and Date settings.	Check that you have set the correct time and date.



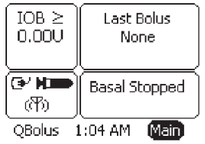
If settings are	Then do this
Correct	Scroll to **Accept** and press **Enter** button.
Incorrect	1. Scroll to highlight the item you want to change. 2. Press **Enter** button. 3. Scroll to the correct setting. 4. Press **Enter** button. 5. Scroll to highlight **Accept**, if not already highlighted. 6. Press **Enter** button.

12. Check your work.	Review that the correct time is displayed on the **Home** screen. Go to the next page to continue setting up your **FreeStyle Aviator System** using the **SETUP WIZARD**.



Procedure (First Time Setup Wizard):

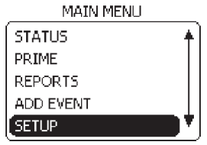
Steps	Do This
1. Go to the SETUP menu.	



a. Notice **Main** is highlighted on the **Home** screen.

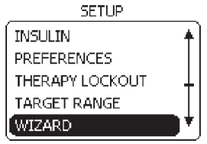
b. Press **Enter** button.

2. Access SETUP WIZARD.



a. Scroll to highlight **SETUP**.

b. Press **Enter** button.



c. Scroll to Highlight **WIZARD.**

d. Press **Enter** button

3. The STEP 1 screen

a. On the **STEP 1** screen, notice **OK** is highlighted.

b. Press **Enter** button.

4. Select language.

a. Notice **Language = English**. (This **CANNOT** be changed.)

b. Notice **Next** is highlighted.

c. Press **Enter** button.

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Steps | Do This

5. Select time format as needed.

TIME/DATE
2:11 PM
Feb 28, 2008
Next Format

TIME/DATE FORMAT
Time = 12 Hour
Date = Mmm dd, yyyy
Accept

OR

TIME/DATE FORMAT
Time = 24 Hour
Date = Mmm dd, yyyy
Accept

Note: *To keep the default time and date settings, press the **Enter** button on **Next** and go to Step 8.*

a. Scroll to highlight **Format**.

b. Press **Enter** button.

c. Decide how you want your companion and pump to display the time.

If you want this format	Then do this
Time = 12 Hour (default)	Notice **Accept** is highlighted. Press **Enter** button.
Time = 24 Hour DATE/TIME 14:11 Feb 28, 2008 Next Format	1. Scroll to highlight **Time**. 2. Press **Enter** button. 3. Scroll to **24 Hour**. 4. Press **Enter** button.

Steps | Do This

6. Select date format.

TIME/DATE FORMAT
Time = 12 Hour
Date = Mmm dd, yyyy
Accept

TIME/DATE FORMAT
Time = 12 Hour
Date = Mmm dd, yyyy
Accept

OR

TIME/DATE FORMAT
Time = 12 Hour
Date = Mmm dd, yyyy
Accept

a. Notice **Date** is highlighted.

b. Press **Enter** button.

c. Decide how you want your companion and pump to display the date.

If you want this format	Then do this
Month Day Year (default) Example: Dec 12, 2007	Notice **Mmm dd, yyyy** is displayed. Press **Enter** button.
Day Month Year Example: 12 Dec 2007	Scroll to **dd Mmm yyyy**. Press **Enter** button.

d. Notice **Accept** is highlighted.

e. Press **Enter** button.

7. Confirm time and date format.

TIME/DATE
2:11 PM
Feb 28, 2008
Next Format

a. Verify that the time and date are correct on the **TIME/DATE** screen.

b. Scroll to highlight **Next.**

c. Press **Enter** button.

8. Set Insulin Profile.

INSULIN PROFILE
Type = Rapid
Action Time = --h --m
Next

Look at the **INSULIN PROFILE** settings on the display. Go to step 9 to make changes.

To keep the default insulin profile settings, press the **Enter** button on **Next** and go to Step 12.

WARNING: *Ask your healthcare professional which type of insulin you will be using and what action time should be set. If you do **NOT** have these settings correct, you may receive the wrong amount of insulin, which may result in adverse medical events or serious injury.*

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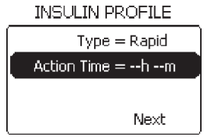
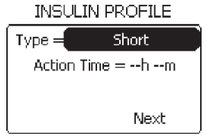
2/9/09 11:29:34 AM

Steps | Do This

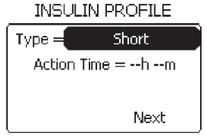
9. Select type of insulin.

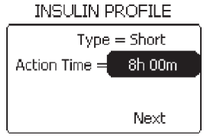




If you use this type of insulin	Then do this
Rapid Acting Insulin Lispro (Humalog) Insulin Glulisine (Apidra) Insulin Aspart (Novolog)	Go to Step 10.
Short acting (Humulin R, Novolin R)	1. Scroll to highlight **Type.** 2. Press **Enter** button. 3. Scroll to **Short**. 4. Press **Enter** button. 5. Go to next step.

10. Select action time.





a. Scroll to highlight **Action Time,** if it is not already highlighted.

Note: *There is a different duration for different types of insulin. The default for* ***Rapid*** *is 5h 00m and the default for* ***Short*** *is 8h 00m. The action time will be per default if not changed.*

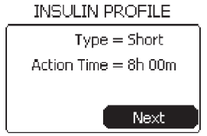
b. Press **Enter** button.

c. Scroll to desired action time, which ranges between 2h 00m – 8h 00m.

d. Press **Enter** button.

Steps | Do This

11. Confirm insulin type and action time is correct.

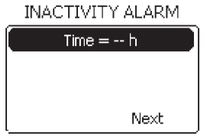


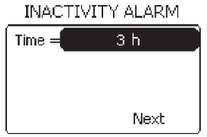
a. Check your settings displayed on the screen.

b. Notice **Next** is highlighted.

c. Press **Enter** button.

12. Set Inactivity Alarm.





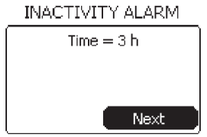
a. Notice **Time** is highlighted.

b. Press **Enter** button.

c. Scroll to the amount of time when you want the pump to alert you that you have had **NO** interaction with the pump. The time ranges between 1h – 24h.

d. Press **Enter** button.

13. Confirm the time for inactivity alarm is correct.



a. Check the time setting on the **INACTIVITY ALARM** screen.

b. Notice **Next** is highlighted.

c. Press **Enter** button.

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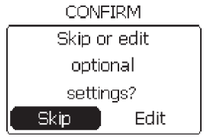
2/9/09 11:29:34 AM

Steps	Do This
14. Skip optional settings.	



a. Notice **Edit** is highlighted.

b. Scroll to highlight **Skip**.

c. Press **Enter** button.

d. If you are setting up your pump for the first time you will not see the "Setup Wizard is complete" screen. Skip to the next task in Section 2.2.

e. Decide what to do next.

If you want to	Then do this
Create your daily **basal program** now (using default settings)	You will skip to the next task **2.2 Create Your Daily Basal Program for the First Time**.
Set up or edit **bolus calculator** options, bolus and basal limits, audio/vibe, low insulin, alarms, **display preferences**, **locked items**, and one-button bolus for first time use	Go to **Section 6: When You're Ready – Optional Settings** for instructions on editing optional settings. Ask healthcare professional for assistance as needed. The table in **Section 12 – Appendix B** shows the default settings for all options.

15. Check your work. You have done this procedure correctly when the time and date are correct, and you have selected all your basic settings correctly.

2.2 Create Your Daily Basal Program for the First Time

Purpose To program your daily basal delivery information into your pump using the **Aviator Companion**.

When Do this procedure:

- Before you use your system for the first time.
- After you have set up basic settings for your pump in **Section 2.1**.

Materials

- Your companion fully charged and paired with your pump.
- Your companion and pump with initial settings programmed.
- Healthcare professional's recommendations for your starting basal pump settings in **Section 12 – Appendix A**.

Helpful Information

- With the **FreeStyle Aviator System**, you are able to program a specific basal rate for each segment of time in your day. These segments are referred to as blocks. Each block of time can be programmed for a specific period of time at a specific rate. There are a maximum of **48 blocks** – one block for each ½ hour of the day.
- Your daily basal program must include **at least ONE block** or time range. If you only enter one block, **the rate will prevail for 24 hours**.
- Your goal is to work with your healthcare professional to find the **basal rates** that work for you. Be prepared to check with your healthcare professional regularly until you find the basal rates that work for you. To edit your daily basal rate, follow the procedures in **Section 7.1**.
- You can also create other basal programs, such as weekend, exercise, or a **temporary basal** in **Section 7**.

Procedure:

Steps	Do This
1. Create your Daily basal program.	

a. Notice **OK** is highlighted.

b. Press **Enter** button.

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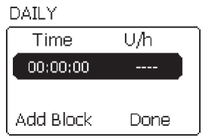
2/9/09 11:29:35 AM

Steps	Do This

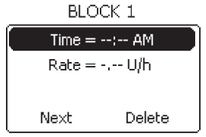
2. Create a basal block.

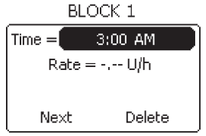


a. Notice that the first block's time line with dashes is highlighted.

b. Press **Enter** button.

3. Set the Start Time for Basal Block 1.





a. Notice **Time** is highlighted.

b. Press **Enter** button.

c. Scroll to select desired start time for basal block 1.

d. Press **Enter** button.

Note: *The range is 12AM – 11:30 PM with 30 minute increments. Your first basal time block will start after midnight at the time you choose. You* ***CANNOT*** *set your last time block later than 11:30PM.*

Look at the following examples:

Example 1:

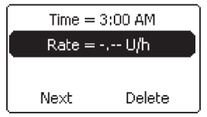
If doctor advises	Create Block	Set Time
One basal rate of 0.5 units/hour	1	Any time you choose – **the basal rate will be the same for 24 hours**.

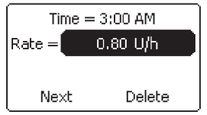
Example 2:

If doctor advises	Create Blocks	Set Time
0.8 units/hour from 3 am to 7 am	1	3 am
0.5 units/hour from 7 am to 10 pm	2	7 am
0.3 units/hour from 10 pm to 3 am	3	10 pm

Steps	Do This

4. Set the Rate for Block 1.





a. Notice **Rate** is highlighted.

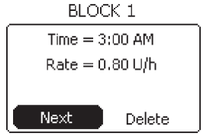
b. Press **Enter** button.

c. Scroll to select Basal Block 1 desired rate of insulin per hour.

Note: *The default basal rate is 0.0 to 2.0 Units/hour. If your basal rate needs to be more than 2.0 Units per hour, you can change it in the* ***SETUP*** *menu. Refer to* ***Section 6.2****.*

d. Press **Enter** button.

5. Confirm Block 1 values are correct.



Verify **Time** and **U/h** values.

If	Then do this
Correct	Notice **Next** is highlighted. Press **Enter** button.
Incorrect and you want to **edit** them	1. Scroll to highlight the item you want to change (**Time** or **Rate**). 2. Press **Enter** button. 3. Scroll to select desired setting. 4. Press **Enter** button.

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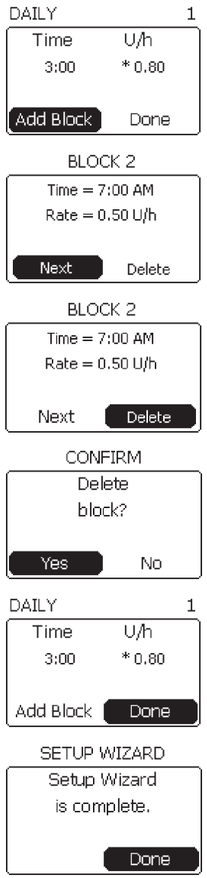
2/9/09 11:29:35 AM

Steps | Do This

6. Decide if you want to add another block or delete the block you just created.



If you want to	Then do this
Add another time block and basal rate	1. Notice **Add Block** is highlighted. 2. Press **Enter** button. 3. Repeat Steps 2 to 5 to add additional time blocks and basal rates. ***Note:*** *You can add up to 48 blocks.* ***Daily*** *is the default, and the * identifies the block associated with the current basal rate.*
Delete the time block and basal rate you just created	1. Notice **Next** is highlighted. 2. Scroll to highlight **Delete.** 3. Press **Enter** button. 4. Notice the **CONFIRM** screen and "**Delete block?**" message displays. 5. Scroll to highlight **Yes.** 6. Press **Enter** button.
Be **finished** with creating time blocks and basal rates for your daily program	***Note:*** If you only enter ***ONE*** block, it will continue for 24 hours. 1. Scroll to highlight **Done**. 2. Press **Enter** button. 3. Notice the screen shows the message "**Setup Wizard is complete.**" and **Done** is highlighted. 4. Press **Enter** button to return to the **Home** screen.

Steps | Do This

Steps	Do This
7. Check your work.	Go to **Section 3.1.2 View Basal Program** and follow the procedure to review the daily **basal program** that you just created.

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2/9/09 11:29:35 AM

2.3 Fill Reservoir

Purpose

To fill the pump's reservoir with insulin for delivery.

When

Do this procedure when you:

- Need to fill your **insulin reservoir**.

Caution: *When your insulin supply is low, there will be a* ***Low Insulin Alert*** *or Insulin Empty alarm. Also, the insulin icon in the* ***Levels*** *panel on the* ***Home*** *screen will show the level of insulin in the reservoir.*

- Want to practice filling the insulin reservoir.

WARNING: *While the pump and infusion set are disconnected from your body, you can practice filling your insulin reservoir with saline until you are comfortable with the procedure.* ***You must dispose of the used infusion set and reservoir after practicing.*** *Do* ***NOT*** *refill the reservoir.*

WARNING: *Insulin that has been degraded by environmental conditions [extreme heat over 104ºF (40º C), extreme cold below 30ºF (-1º C), has clots, etc.] may cause adverse medical events or serious injury. Discard any insulin that has been exposed to extreme temperatures.*

WARNING: ALWAYS disconnect *your pump and infusion set from your body before removing the insulin reservoir from the pump. There is a possibility of occurrence of adverse medical events or serious injury if the reservoir is* ***NOT*** *installed in the pump and the reservoir is accidentally pressed or hit.*

Materials

Gather these materials before you begin:

- Package containing the reservoir with the removable plunger handle attached to the reservoir plunger and a reservoir protective cap (female luer cap).

WARNING: *Your pump's reservoir is for* ***single use only****. Use only the* ***Aviator-****compatible reservoir intended for your pump. Do* ***NOT*** *substitute with any other reservoir. Do* ***NOT*** *reuse the plastic reservoir. It is intended to work best when replaced after one use.*

Insulin (or water or saline, if you are practicing).

WARNING: *Do* ***NOT*** *allow any insulin or fluid to get into the reservoir compartment.*

WARNING: *Before filling the reservoir, make sure your insulin is at room temperature to limit the amount of bubbles. If you have questions about the correct temperature, consult your insulin manufacturer's product insert or your healthcare professional.*

WARNING: *Use only rapid-acting or short-acting U-100 insulin with the* ***Aviator Pump****. Use of another type of insulin may result in adverse medical events or serious injury.*

The following insulins have been tested by Abbott Diabetes Care, Inc. and found to be safe for use in the Aviator Pump: Humalog ®, Apidra®, Novolog®, and regular insulin. Before using a different insulin with this pump, check the insulin label to make sure the insulin can be used with the pump.

- Package for the **filling needle**.

Use in conjunction with one of the following:

Tyco Healthcare Kendall Monoject™ 22 GA (0.7mm) x 1" (25.4mm) -
Part Number 8881 250222

Tyco Healthcare Kendall Monoject™ 23 GA (0.6mm) x 1/2" (12.7mm) -
Part Number 8881 250263 - (Available in USA only)

- Package for the **infusion set** containing the infusion set with an attached **reservoir cap**.
- Soap and water
- Alcohol swab

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Helpful Information

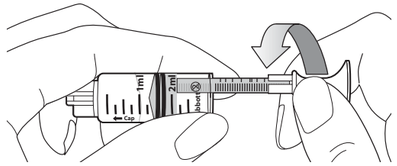
Caution: *You **MUST** replace the pump's reservoir and infusion set each time you replenish your insulin supply.*

Caution: *You **MUST** change your infusion set **every three days or sooner** according to your healthcare professional's advice. You may need to change your infusion set more frequently if it becomes dislodged, if skin irritation or signs of infection develop, signs of poor control appear, or at the advice of your healthcare professional.*

Tip: The insulin reservoir is packaged with the **reservoir plunger handle** attached to the plunger tail.

If it is necessary to reattach a plunger handle that has become disconnected, follow these steps:

1. Hold the plunger handle so the 3 prongs resemble 2 eyes and a nose.
2. Place the serrated side of the **reservoir plunger** in the space between the nose and the eye to the viewer's right. Make sure the plunger makes contact with the surface of the plunger handle in between the eyes and the noses.



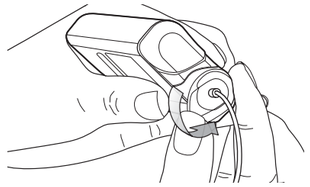
3. Holding the plunger handle stationary, twist the reservoir counter-clockwise towards you.
4. If done correctly, the groove on the back of the plunger should be positioned between the two eyes.

Procedure:

Steps	Do This
1. Decide if you are filling a reservoir for the first time.	

If you are	Then do this
Filling the reservoir for the first time	Go to Step **4**.
Removing a used reservoir to fill a new reservoir	Go to Step **2**.

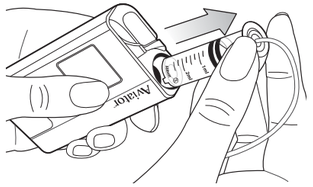
Steps	Do This
2. Remove your pump and infusion set.	***WARNING:*** • ***You must STOP your basal delivery before removing the reservoir.*** • ***Always disconnect your pump and infusion set from your body before removing the insulin reservoir from the pump***. Follow the procedure described in your infusion set's instructions, or your healthcare professional. ***WARNING:*** • *Do **NOT** use an infusion set if the sterile packaging has been damaged.* • *Check the sterile supplies for the expiration date. Do **NOT** use any expired components.*
3. Remove the insulin reservoir from the pump.	



a. Locate the insulin reservoir cap on the upper left side of your pump.

b. Place your thumb in the groove on the face of the reservoir cap.

c. Gently rotate the handle counter-clockwise 90 degrees, or until you cannot turn it any further.



d. Gently pull out on the handle to remove the insulin reservoir.

Note: *Do **NOT** force. You may have to wiggle the insulin reservoir to loosen it enough for you to remove it.*

Dispose of the empty reservoir and connected infusion set.

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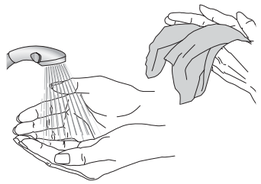
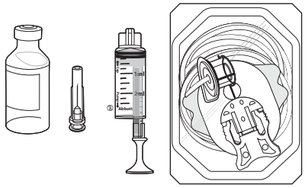
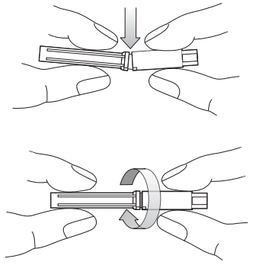
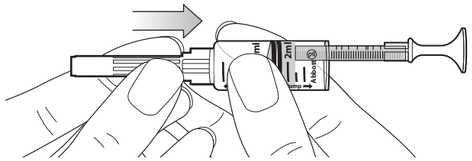
Steps	Do This
4. Wash your hands and gather materials.  	**a.** Wash your hands vigorously with soap and warm water. ***Caution:*** *Use aseptic techniques when filling the reservoir and connecting the infusion set. Ensure everything is clean and sterile to prevent infection.* **b.** Place the following items in front of you: • Insulin vial (or water or saline, if you are practicing) • Alcohol swab (**NOT** pictured) • New filling needle package (**NOT** pictured) • New **Aviator Reservoir** package (**NOT** pictured) • New infusion set package
5. Open the sterile packaging for a new filling needle 	**a.** DO NOT USE IF CAP SEAL IS BROKEN. Caution: • Align cap seal downward away from face (eyes), body and patient. Break tamper-evident cap seal by twisting the cap or by applying a downward snap.
6. Open the sterile packaging for a new reservoir	**a.** Open the packaging (NOT pictured). **b.** Take out the reservoir and leave the protective cover inside the package for later.

Steps	Do This
7. Insert the filling needle with its protective cover attached into the tip of the reservoir so that it is secure.	
8. Clean the top of the insulin vial with an alcohol swab.	
9. Open the sterile packaging for a new infusion set.	**a.** Open the packaging. **b.** Leave the infusion set inside the packaging until later.
10. Remove the protective cap from the needle and discard	

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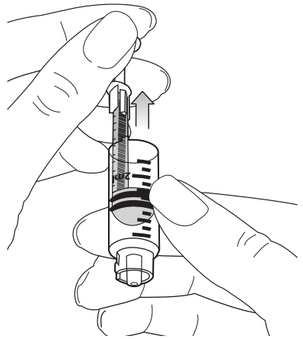
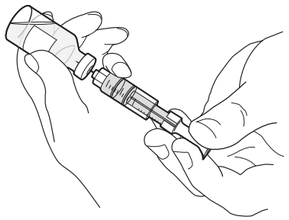
Steps	Do This
11. With your clean reservoir in hand, pull back on the plunger to draw air into the reservoir. 	***Note:*** *The amount of air drawn into the reservoir should be equal to the amount of insulin you intend to draw into the reservoir.*

12. Pierce the needle through the top of the insulin vial	While holding the insulin vial and reservoir upright, gently push down on the reservoir so that the needle pierces through the top of the insulin vial.
13. Push the plunger handle downward to expel the air into the insulin vial.	While keeping the insulin vial, filling needle, and attached reservoir **on a flat surface**, push the plunger handle downward so that the air you drew into the reservoir is expelled into the insulin vial.
14. Fill the insulin reservoir. 	**a.** While keeping pressure on the end of the removable handle, turn the insulin vial upside down. **b.** Next, release the pressure on the end of the plunger handle and allow insulin to flow into the reservoir. **c.** Gently pull down on the plunger handle until enough insulin is in the reservoir.

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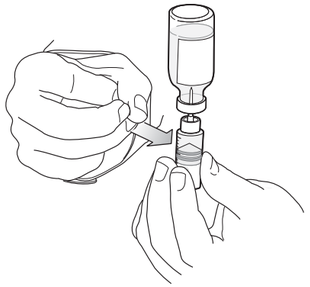
15. Remove air bubbles in the reservoir.



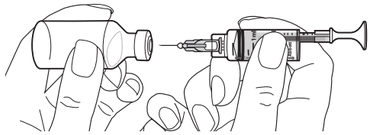
a. Look for any large air bubbles in the reservoir and remove them before use.

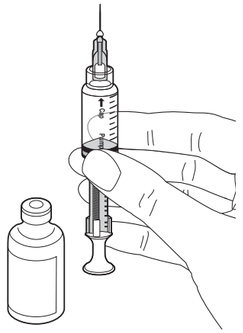
b. You can do this by gently tapping on the side of the reservoir with your fingernail to loosen any air bubbles

WARNING:
- *You must remove all air bubbles in the reservoir before proceeding. Champagne-sized bubbles may remain. Delivery of air bubbles can result in unexpected hyperglycemia.*

c. Remove the collected air bubbles by pushing up on the plunger handle.

16. Pull reservoir and attached filling needle out of the insulin vial.





a. Once the reservoir is filled with the proper amount of insulin, turn the set of items in your hands so that it is parallel to the flat surface.

b. While keeping your finger and thumb on the insulin vial, gently pull the reservoir and attached filling needle out of the insulin vial.

c. Put the insulin vial on the flat surface.

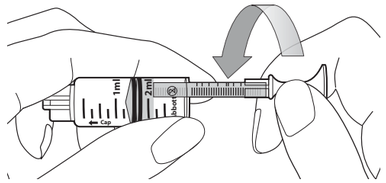
d. Hold the reservoir so that the reservoir tip points up.

Note: *To ensure sterility, do **NOT** touch the tip of the insulin reservoir.*

17. Remove the needle from the reservoir by gently twisting it off. Dispose of the needle in a sharps container.

Caution: *RISK OF NEEDLESTICK INJURY. Used needles may be contaminated and should be disposed of in puncture-resistant (sharps) containers. Do not resheath used needles. Handle per national/ institutional guidelines and policies. Follow local waste disposal regulations when disposing of sharps containers.*

18. Disconnect plunger handle.

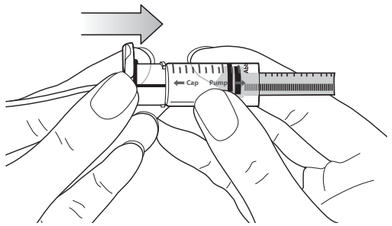


a. Twist the plunger handle clockwise to disconnect it from the reservoir plunger.

Note: *Check to make sure you still have your desired amount of insulin, and that the reservoir is free of air bubbles.*

b. Dispose of the plunger handle.

19. Attach reservoir cap of infusion set to the new reservoir.



a. Carefully take the infusion set out of the infusion set packaging.

b. Ensure that the black mark on the side of the reservoir cap aligns with the black line on the side of the reservoir.

WARNING:
- *Do **NOT** twist the reservoir cap onto the reservoir. Just snap it on and make sure the alignment guides match up.*
- *Do **NOT** put the reservoir into the pump without first putting on the reservoir cap.*
- *Check for any damage to the catch feature before mating the infusion set reservoir cap to the reservoir barrel.*

c. Attach the infusion set's reservoir cap to the tip of the new reservoir. Ensure that the infusion set reservoir cap snaps onto the reservoir barrel.

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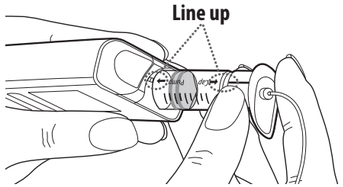
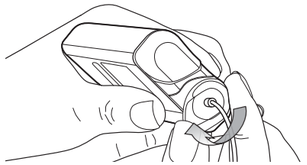
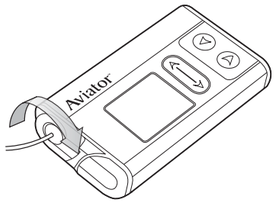
20. Insert the insulin reservoir into the pump.







a. Line up the reservoir with the **reservoir compartment** by placing the black dotted line with the arrow on the reservoir in line with the white line on the pump.

WARNING:

- *Do **NOT** hold the plunger while placing the reservoir into the pump, or you may accidentally deposit insulin into the tubing and cause problems with insulin delivery and possible adverse events or serious injury.*

WARNING:

- *Do **NOT** force the reservoir into the pump. Make sure the black reservoir alignment mark is lined up with the pump alignment mark and gently wiggle into place.*

WARNING:

- *Do **NOT** allow any insulin or fluid into the reservoir compartment.*

b. Slide the reservoir back into the reservoir compartment.

c. Gently wiggle it if necessary until it drops fully into place.

***Tip:** If you hold the reservoir compartment vertically, the reservoir will slide into the pump once you have turned it into the correct position. There is **NO** need to push the reservoir into the pump.*

d. Use your thumb or finger to rotate the cap handle 90 degrees clockwise, or until it aligns with the side of the pump.

21. Return the insulin vial to its storage location.

2.4 Prime Pump and Infusion Set

Purpose

To prime the pump, infusion set tubing and cannula using the **Aviator Companion**, so that the pump is ready to deliver insulin.

When

Do this procedure when you:

- Change your infusion set
  - Before connecting the infusion set to your body – to remove the air from the tubing.
  - Just after connecting the infusion set to your body – to replace the small amount of air that was in the cannula (soft tubing that remains in your body to deliver insulin).
- Notice air in your tubing and have disconnected the infusion set from your body – to remove the air from the tubing.

***WARNING:** Use **ONLY** the **Aviator** infusion sets intended for your pump. **NOT** using the correct infusion set may result in adverse medical events or serious injury.*

***WARNING:** You need to install the reservoir in the pump and prime tubing before attaching infusion set to body.*

***WARNING:** If infusion set is attached to your body when priming, this may result in accidental delivery of insulin and possible adverse medical events or serious injury.*

***WARNING:** If reservoir, infusion set tubing or cannula is improperly primed, this may result in delivery errors and adverse medical events or serious injury.*

***WARNING:** Prime infusion set cannula after every infusion set change.*

Materials

- Your companion with battery charged and initial settings programmed.
- Your pump with the battery installed and reservoir filled.
- Your companion and pump already paired.
- A Unomedical comfort™, comfort short™ or inset™ II infusion set

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Helpful Information

- When priming your pump, you are actually priming the different parts of the **Aviator Insulin Delivery System**, which is the infusion set tubing and the cannula. Priming ensures that there is insulin in the infusion set tubing and cannula.

Note: *It is critical that all priming is complete before beginning basal delivery.*

*Priming ensures that all the parts of the insulin pump system are ready to deliver insulin when you attach it to your body. If any air remains in the tubing when you begin your basal delivery or deliver a bolus, you will **NOT** receive insulin, and you will receive air. This could result in possible adverse medical events or serious injury.*

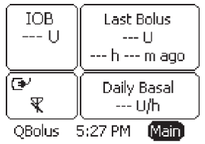
*Steps in this procedure **MUST** be completed; otherwise you will **NOT** be delivering insulin to your body, resulting in high blood glucose.*

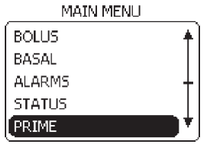
- **Make sure you see a small amount of insulin (one or two drops) appearing at the end of the infusion set needle to confirm that the infusion set is primed.** You may need to increase the amount of the prime to at least 4 – 6 units.

Caution: *You **MUST** change your infusion set **every three days or sooner** according to your healthcare professional's advice. You may need to change your infusion set more frequently if it becomes dislodged or if skin irritation or signs of infection develop, or blood appears in your tubing.*

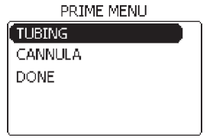
Procedure:

Steps	Do This
1. Access PRIME MENU from Home screen.	**a.** Notice **Main** is highlighted. **b.** Press **Enter** button. **c.** Scroll to highlight **PRIME**. **d.** Press **Enter** button.

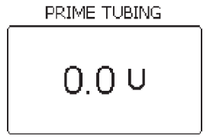


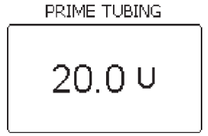


Steps	Do This
2. Select TUBING.	**a.** Notice **Tubing** is highlighted. **b.** Press **Enter** button. ***WARNING:*** *If infusion set is attached to your body when priming, this may result in accidental delivery of insulin and possible adverse medical events or serious injury.* **c.** Notice **WARNING** screen and "**Detach infusion set from body**." message displays. **d.** Notice **OK** is highlighted. **e.** Confirm that the infusion set is **NOT** attached to your body. **f.** Press **Enter** button.



3. Prime Tubing.	**a.** Scroll to select desired units of insulin to prime tubing. ***Note:*** *Check that you are delivering a large enough volume of insulin for priming to be completed in both the tubing and cannula. If a tiny amount of insulin has **NOT** come out of the end of the tubing, you may need to increase the amount of the prime to at least **4 – 6** Units.* *You will need to prime approximately **20** Units if you use the **LONGER** tubing. The amount of insulin required to prime will vary depending on the type of infusion set you use. The default is 0.0 U to a maximum of 30.0 U.* **b.** Press **Enter** button. ***Note:*** *You will hear two beeps (from the pump).* **c.** Verify that the pump is delivering insulin to prime tubing. ***Note:*** *As the prime is delivered, the Units will be counted off. As your pump is priming, you should be watching for a small amount (one or two drops) of insulin to emerge from the end of the connector needle. When this occurs, priming your tubing is complete.* ***Tip:*** *You may find it easier to see the insulin flowing through the tubing if you hold the tubing against a dark background, such as a dark table or towel.*





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Steps | Do This

4. Decide what to do next.

DELIVERING
Prime
12.9 of 20.0U
Stop

If you want to	Then do this
Finish priming the tubing	Allow pump to complete priming and automatically return to **PRIME MENU** screen. ***Note:*** *You will hear two more beeps when prime is finished. If the amount primed was **NOT** sufficient, you will return to the **Home** screen. Go back to Step 3.* Continue to Step 5.
STOP priming the tubing	1. Notice **Stop** is highlighted 2. Press **Enter** button to return to the **PRIME MENU** screen. ***Note:*** *If the amount primed was **NOT** sufficient before stopping the prime, you will automatically return to the **Home** screen. Go back to Step 3.* 3. Scroll to highlight **Done**. 4. Press **Enter** button. You have **NOT** primed the tubing; go back to Step 1 if you want to prime the tubing and infusion set.

Note: *It is important that you prime the tubing sufficiently to engage the reservoir. Ensure insulin is flowing through the tubing and emerging from the end of the connector needle or inserter needle, depending upon the set you are using.*

5. Attach and prepare infusion set for priming.

If you are using	Then do this
Inset™ II	Attach the inset™ II infusion set to your infusion site, following the infusion set's instructions.
Comfort™ or comfort short™	Attach cannula housing to your body, following the infusion set's instructions. Connect the tubing to the cannula housing, following the infusion set's instructions.

Note: *Select infusion sites away from scarred or infected areas, and rotate infusion site locations regularly.*

Steps | Do This

6. Select CANNULA from the PRIME MENU.

PRIME MENU
TUBING
CANNULA
DONE

a. Notice **Cannula** is highlighted.

Note: If ***Cannula*** is ***NOT*** already highlighted, scroll to highlight ***Cannula*** from the ***PRIME MENU***.

b. Press **Enter** button.

7. Prime Cannula.

PRIME CANNULA
0.20 U

a. Scroll to select desired units of insulin to prime the cannula.

Note: *The range is between 0.00 U and 1.00 U. The specific units to prime the cannula will be listed in the package insert of your infusion set (e.g. for the comfort™ and comfort short™, it is 0.5 to 1.0 units). The default for the amount will appear on the screen for the last amount used to prime the cannula. If you are using a different set this time, you will need to verify that the amount listed is correct. Ask your healthcare provider.*

b. Press **Enter** button.

Note: *You will hear two beeps (from the pump) when priming starts.*

c. Hear the pump delivering insulin to prime the cannula and see insulin emerging from the end of the connector needle.

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Steps | Do This

8. Decide what to do next.

If you want to	Then do this
Finish priming the cannula	1. Allow pump to complete delivering prime. **Note:** *You will hear two more beeps when prime is finished.* 2. Go to the next step.
STOP priming the cannula	1. Notice **Stop** is highlighted 2. Press **Enter** button. 3. Go to the next step.

9. Decide whether to start daily basal now, or wait till later.

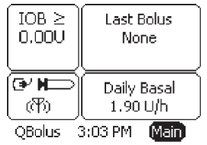
Note: *If you inserted a new reservoir and went directly to prime cannula, make sure the amount is enough to engage the reservoir and insulin emerges from the end of the connector needle, or else the pump will return to the* ***Home*** *screen instead of prompting you to start basal delivery. Also* ***make sure there are NO bubbles in the tubing****.*

Notice the **CONFIRM** screen and "**Start Daily Basal?**" message displays immediately after cannula priming is complete.

If you want to	Then do this
Start your daily basal **NOW**	1. Scroll to highlight **Yes**. 2. Press **Enter** button to return to the **Home** screen. ***Note:*** *You will hear 4 beeps and the pump will vibrate twice.* 3. Go to Step 10 to check your work.
Start your daily basal **LATER**	1. Notice **No** is highlighted. 2. Press **Enter** button. ***Note:*** *The pump screen will return to the* ***Home*** *screen.* 3. Review the **Basal panel** on the **Home** screen showing that Daily basal has **NOT** started. 4. Check with your healthcare professional to decide when you should start your daily basal.

Steps | Do This

10. Check your work.



Check that your Daily basal is started in the **Basal** panel on the **Home** screen. The name of the active basal program and the units will display in the **Basal** panel.

Note: *If you started your daily basal here from your pump, there is* ***NO*** *need to also start basal delivery from the companion.*

WARNING: *Check blood glucose 2-3 hours after inserting a new infusion set to make sure your* ***blood glucose level*** *is normal.*

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3 Using Your System – The Basics

3.1.1 Start Basal Delivery

Purpose

To start or restart your basal delivery using your **Aviator Companion** from the **Main** menu. SKIP this task if basal delivery is already started.

When

Do this procedure:

- Whenever you need to start your basal delivery program, if you have **NOT** done so after priming your pump and infusion set.
- Whenever you need to restart your basal delivery after setting additional options.

WARNING: *Accurate basal rate programming and appropriate selection of the active Basal Program are necessary to avoid adverse medical events or serious injury.*

Materials

- Your companion with battery charged and initial setup and **basal settings** programmed.
- Your pump with the battery installed and initial setup and basal settings programmed.
- Your companion and pump already paired.
- Your reservoir filled and inserted into pump.
- Your infusion set and cannula primed.
- Healthcare professional's assistance and recommendations for your basal settings.

Helpful Information

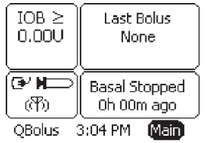
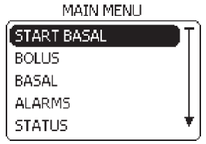
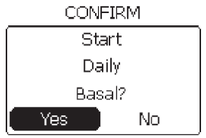
- Basal rates are programmed to deliver insulin continuously over 24 hours. The rate programmed is intended to keep the blood glucose within your target range between meals and overnight. The basal rate is measured in units per hour (U/hr).
- Basal rates can vary throughout the day (e.g. your basal rate while sleeping may be different than when you are awake), and may be different on different days (e.g. weekdays versus weekends). The **Aviator Pump** can accommodate up to **4** different 24-hour basal rate patterns (e.g. one for weekdays, one for workout days, and one for weekends).
- With the **Aviator Pump**, you are able to program a specific basal rate for each segment of time in your day. These segments are referred to as blocks. Each block of time can be programmed for a specific period of time at a specific rate. There are a maximum of **48 blocks** – one block for each ½ hour of the day.
- Your pump should always be delivering basal insulin.

Before you start your basal insulin delivery for the first time, make sure you have completed the following tasks:

- Set up your pump using the **SETUP WIZARD** (**Section 2.1**).
- Fill your insulin reservoir (**Section 2.3**)
- Prime your infusion set and cannula (**Section 2.4**).

Note: If you need to change your basal options such as basal insulin increment and basal insulin maximum, refer to ***Section 6.2***, and obtain assistance from your healthcare professional.

Procedure:

Steps	Do This
1. Access MAIN MENU from Home screen.  	**a.** Notice **Main** is highlighted. **b.** Press **Enter** button.
2. Start Basal.  	**a.** Notice **Start Basal** is automatically highlighted. **b.** Press **Enter** button.
3. Confirm Start Basal.  	**a.** Notice the **CONFIRM** screen and **"Start Daily Basal?"** message displays. **b.** Determine what to do next.

If you want to	Then do this
Start your basal delivery now	1. Scroll to highlight **Yes**. 2. Press **Enter** button. 3. Notice the pump automatically returns to the **Home** screen. ***Note:*** *You will hear 4 quick beeps and feel 2 short vibrations from the pump.*
Cancel starting your basal delivery	1. Notice **No** is already highlighted. 2. Press **Enter** button. 3. Review the **Basal** panel on the **Home** screen showing that basal is **NOT** started. 4. Check with your healthcare professional to decide when you should start your daily basal.

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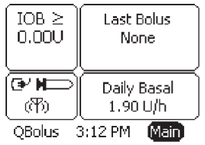
Steps	Do This
4. Check your work. 	If you **started** your basal delivery, review the name of the current basal program and the insulin rate displayed in the **Basal** panel on the **Home** screen. If you did **NOT** start your daily basal, review the **Basal** panel on the **Home** screen showing that the basal has **NOT** started.

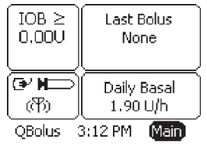
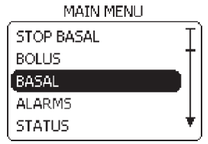
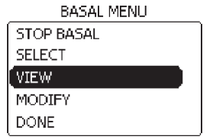
3.1.2 View Basal Program

Purpose	To view your existing basal program(s) and specific time blocks and basal rates using your **Aviator Companion**.
When	Do this procedure: • Whenever you need to view your basal program settings after creating or editing them.
Materials	• Your companion and pump with basal delivery started. • Healthcare professional's recommendations for your basal settings for the pump. • Your personalized Table of Settings in **Appendix A**.

Helpful Information

- You **CANNOT** select a different basal program to be the active basal program from the **VIEW program** option nor edit any basal rates or times.

Procedure:

Steps	Do This
1. Access BASAL MENU from Home screen. 	**a.** Notice **Main** is highlighted. **b.** Press **Enter** button.
2. Select BASAL. 	**a.** Scroll to highlight **BASAL**. **b.** Press **Enter** button.
3. Select VIEW option. 	**a.** Scroll to highlight **VIEW**. **b.** Press **Enter** button.

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Steps	Do This
4. Select basal program to view. VIEW PROGRAM *Daily Done	**a.** Notice ***Daily** is highlighted. ***Note: Daily** is the default, and the * identifies the current active basal program. Scroll to view another program as appropriate, if you have created other basal programs.* **b.** Press **Enter** button.
5. Review basal program time blocks and basal rates. DAILY 1/1 Time U/h 3:00 AM * 1.90 Done VIEW BLOCK 1 Time = 3:00 AM Rate = 1.90 U/h Next DAILY 1 Time U/h 3:00 AM * 1.90 Done	**a.** Scroll to highlight and select a time block to view. ***Note:** The * represents the block/rate that is associated with the current time.* **b.** Press **Enter** button. **c.** View the time and rate for the block. **d.** Notice **Next** is highlighted. **e.** Press **Enter** button. **f.** Scroll to select and review other basal time blocks and basal rates that were created as needed. **g.** Scroll to highlight **Done** when you are done reviewing. **h.** Press **Enter** button to return to **Home** screen.
6. Check your work.	**i.** You have verified that the basal program has the correct basal time blocks and basal rates.

3.1.3 Stop Basal Delivery

Purpose	To stop your basal delivery using your **Aviator Companion**.
When	Do this procedure: • Whenever you need to stop your basal delivery to replace a battery, refill an insulin reservoir, or change your infusion set.
Materials	• Your companion and pump with basal delivery started. • Healthcare professional's recommendations for your basal settings.

Helpful Information

***WARNING:** You should **NOT** stop your daily basal delivery program without consulting your healthcare professional. If NO basal insulin is being delivered, this can lead to hyperglycemia and DKA unless insulin is delivered by another means. Be sure to discuss with your healthcare professional regarding how long you can stop your basal rate.*

- If you are stopping a temporary basal program, basal delivery for your active basal program will resume. Refer to **Section 7.6** for more information on temporary basal programs.
- You will perform this task using the companion. Refer to **Section 12** to stop basal delivery using your pump.

Procedure:

Steps	Do This
1. Access *BASAL MENU* from Home screen. IOB ≥ 0.00U Last Bolus None Daily Basal 1.90 U/h QBolus 3:22 PM Main	**a.** Notice **Main** is highlighted. **b.** Press **Enter** button.
2. Stop Basal. MAIN MENU STOP BASAL BOLUS BASAL ALARMS STATUS	**a.** Notice **Stop Delivery** is highlighted. **b.** Press **Enter** button.

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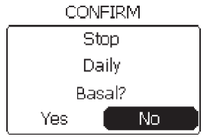
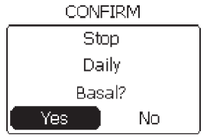
Steps	Do This
3. Confirm Stop Basal.	***Note:*** *If an* ***extended bolus*** *is in progress, you must stop the bolus first. Refer to* ***Section 3.2.3*** *to* ***stop bolus*** *delivery.* ***Note:*** *If a temporary basal is in progress, you must stop the temporary basal first before stopping the active basal.*

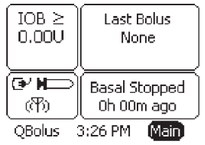




- Notice the **CONFIRM** screen and "**Stop Daily Basal?**" message displays.
- Determine what to do next.

If you want to	Then do this
STOP your basal delivery	1. Scroll to highlight **Yes**. 2. Press **Enter** button to return to the **Home** screen. ***Note:*** *You will hear 2 quick beeps from the pump when basal stops.* 3. Go to Step 4.
Cancel stopping your basal delivery	1. Notice **No** is highlighted. 2. Press **Enter** button. 3. Review the **Home** screen and see that basal delivery has **NOT** stopped and is still delivering.

4. Check your work.



If you	Then you will see this
STOPPED your basal delivery	"**Basal Stopped**" displays on the **Home** screen. **RESTART** basal. Refer to **Section 3.1.1** as needed.
Cancelled stopping your basal delivery	The current basal delivery program and insulin rate still displays in the **Basal** panel on the **Home** screen.

3.2.1 Deliver a Manual, Normal Bolus

Purpose

To deliver a **normal bolus** from your **Aviator Companion** to cover a meal or lower a high glucose reading.

When

Do this procedure:

- Whenever you need to deliver a normal bolus for food or to correct a high glucose level and you do **NOT** want to use the bolus calculator.

WARNING: *Appropriate and accurate bolus dosing is necessary to avoid possible delivery errors that may result in adverse medical events or serious injury.*

Materials

- Your companion completely set up.
- Your pump completely set up and delivering basal insulin.
- Healthcare professional's recommendation for your bolus settings for the pump and assistance from Diabetes Educator or pump trainer as needed.
- Your personalized Table of Settings in **Section 12** - **Appendix A.**

Helpful Information

Note: *In order to follow the directions and use the functions described in this section, you should have already set up your companion using the* ***SETUP WIZARD****. Detailed instructions for setting up your companion can be found in* ***Section 2.1*** *and* ***Section 6.1****.*

- You MUST **START** basal delivery before you deliver any boluses.
- Bolus insulin is an amount of insulin your body needs at any specific time in order to deal with food intake and/or **blood glucose levels** that are elevated above your personal safety threshold. You can record your personalized bolus recommendations in the Table of Settings in **Appendix A**.
- The companion looks at the amount of insulin that is still active from earlier boluses. This amount is displayed as insulin on board (IOB). As the insulin gets used in the body, the amount of IOB goes down. Your IOB will be displayed in the **panel** on the **Home** screen.
- There may be times when there is not enough information to calculate an accurate IOB level. In those instances, a question mark will appear next to the insulin on board reading indicating that the IOB calculation may **NOT** have sufficient information to accurately calculate IOB.
- The companion offers several other options for administering a bolus. Additional bolus features include Extended and **Dual Bolus** types, and Bolus Calculators. Additional bolus features include Extended and Dual Bolus types, and Bolus Calculators. You may choose to use these options or simply use the **Manual Bolus** feature.
- Personal **bolus options** should already have been set up via the **SETUP WIZARD**. You should record your personal list of bolus options in the Table of Settings in **Appendix A**. These options can be modified in the **SETUP WIZARD**.

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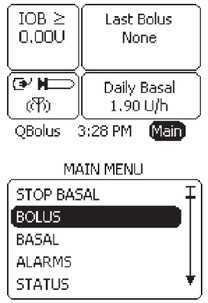
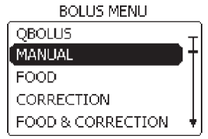
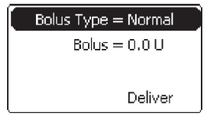
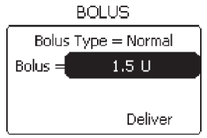
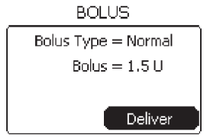
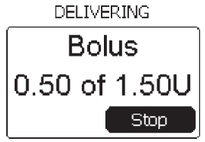
Procedure:

Steps	Do This
1. Access BOLUS MENU from MAIN MENU. 	**a.** Notice **Main** is highlighted. **b.** Press **Enter** button. **c.** Scroll to highlight **BOLUS**. **d.** Press **Enter** button. ***Note:*** *You can also scroll to the* ***Bolus panel*** *on the* ***Home*** *screen and press* ***Enter*** *to access the* ***BOLUS MENU****.*
2. Select MANUAL bolus. 	**a.** Scroll to highlight **MANUAL**. **b.** Press **Enter** button.
3. Select Normal Bolus Type. 	**a.** Notice **Bolus Type** is highlighted. **b.** Press **Enter** button. **c.** Notice **Normal** is highlighted. **d.** Press **Enter** button. ***Note:*** *It is possible to access other types of bolus delivery. If you accidentally scroll to another bolus type, make sure you scroll back to* ***Normal****.*

Steps	Do This
4. Set Normal Bolus. 	**a.** Notice **Bolus** is highlighted. **b.** Press **Enter** button. **c.** Scroll until the desired bolus number of units display. ***Note:*** *You* ***CANNOT*** *deliver a bolus greater than the maximum bolus amount you have set in your pump. Refer to* ***Section 6.1*** *for setting maximum bolus options.* **d.** Press **Enter** button.
5. Confirm Bolus Type is Normal and Bolus units are correct. 	**a.** Review the **Bolus Type** and **Bolus** units on the screen. **b.** Scroll up to select and make edits if needed. **c.** Notice **Deliver** is highlighted. **d.** Press **Enter** button.
6. Deliver Normal bolus. 	***Note:*** *You will hear 2 quick beeps or feel 2 short vibrations from the pump.* Notice that the bolus starts to deliver.

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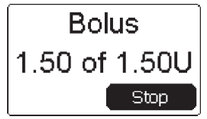
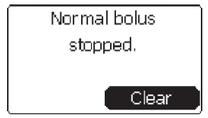
Steps	Do This

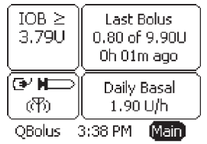
7. Decide what to do next.





If you want to	Then do this
Finish delivering the normal bolus	Allow the normal bolus to deliver to the amount that was set. ***Note:*** *Once the bolus has finished delivering, you will hear 2 more quick beeps or feel 2 more short vibrations and then you will return to the* ***Home*** *screen.* Go to Step 8 to check the bolus delivery.
STOP the normal bolus delivery immediately	1. Notice **Stop** is highlighted. 2. Press **Enter** button. 3. Notice **STOPPED ALERT** screen appears and "**Normal bolus stopped.**" message displays. 4. Notice **Clear** is highlighted. 5. Press **Enter** button to clear the message and return to the **Home** screen. 6. Notice that the last bolus that you stopped is displayed in the **Bolus** panel.

8. Check your work.



Review the amount and time of the **Last Bolus** that was delivered, on the **Bolus** panel of the **Home** screen.

3.2.2 Stop Bolus Delivery

Purpose	To stop a normal bolus delivery using the **Enter (Jogwheel)** button on your **Aviator Companion** or **Aviator Pump**.
When	Do this procedure: • Whenever you want to stop a normal bolus in progress quickly and discreetly.
Materials	• Your pump in the process of delivering a normal bolus.

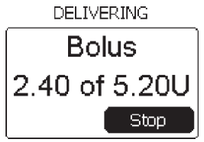
Helpful Information

- The **Stop** item that displays on the **MAIN MENU**, **BOLUS MENU**, and **SELECT PROGRAM** screens stop **ONLY** an **extended bolus** (**Section 8.1**).

Procedure:

Steps	Do This

1. Notice Normal bolus is in progress.



a. Notice on the screen that the bolus delivery is in progress, and **Stop** is highlighted.

b. Press the **Enter (Jogwheel)** button to immediately stop the delivery.

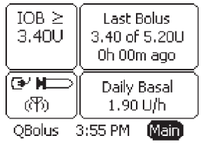
2. Stop the normal bolus delivery.

a. Notice the **STOPPED ALERT** screen pops up and "**Normal bolus stopped**." message displays.

b. Notice **Clear** is highlighted.

c. Press **Enter** button to clear the message and return to **Home** screen.

3. Check your work.



Review the **Last Bolus** amount and time that you just stopped, on the **Bolus** panel of the **Home** screen.

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3.2.3 View Bolus History

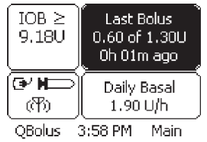
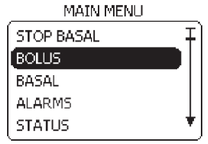
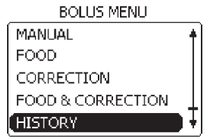
Purpose	To view your last 10 boluses delivered by your pump, using the **Aviator Companion**.
When	Do this procedure: • Whenever you need to review a previous bolus that was delivered by your pump, using the companion.
Materials	• Your companion fully operating. • Your pump fully operating.

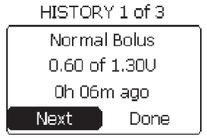
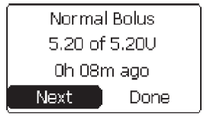
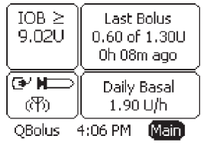
Helpful Information

Note: *In order to follow the directions and use the functions described in this section, you should have already set up your pump using the* ***SETUP WIZARD****. Detailed instructions for setting up your pump can be found in* ***Section 6.1****.*

- The **Bolus History** option gives a listing of your last 10 boluses.

Procedure:

Steps	Do This
1. Access BOLUS MENU from MAIN MENU.  	**a.** Notice **Main** is highlighted. **b.** Press **Enter** button. **c.** Scroll to highlight **BOLUS**. **d.** Press **Enter** button. ***Note:*** *You can also scroll to the* ***Bolus*** *panel on the* ***Home*** *screen and press* ***Enter*** *to access the* ***BOLUS MENU****.*
2. Access Bolus History. 	**a.** Scroll to highlight **HISTORY**. **b.** Press **Enter** button.

Steps	Do This
3. Review the last bolus.  	**a.** Review the last bolus that the pump administered. **b.** Decide what to do next. If you: Want to review another bolus — Then do this: 1. Notice **Next** is highlighted. 2. Press **Enter** button. 3. Repeat Step 3 to review up to 10 previous boluses. **Note:** When you are reviewing **BOLUS HISTORY 2** through 10, you can press the **Back** button to go back to the previous history screen. If you: Have finished reviewing your bolus history — Then do this: Scroll to highlight **Done**. Press **Enter** button to return to the **Home** screen.
4. Check your work. 	Verify that you have obtained the information about your bolus history as needed. You will see the amount and time of your **Last Bolus** on the **Home** screen. ***Note:*** *If you have* ***Magnify*** *display option turned on (in* ***Section 6.1****), you will only see the time of the last bolus.*

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4 Integrating the System into Everyday Life

4.1 Daily Living

Purpose	To decide if, where, when, and how to wear your **Aviator Pump** during daily activities, and how to carry and use your **Aviator Companion**.
When	When you start to carry and use your companion every day. • When you are getting ready to wear your pump while: • Doing normal daytime activity • Sleeping • Bathing or showering • Exercising or playing sports • Swimming • Engaging in sexual intimacy • Traveling • Receiving medical treatment or care, including X-ray or MRI
Materials	Read all the information in this section before you begin using your system.

Helpful Information

- Refer to **Section 6.7** for instructions on performing a self test on your companion.
- Do **NOT** drop your companion or pump, or hit it against hard surfaces. If this occurs, see **Section 9** to troubleshoot **system error** or problems with your system.
- If your companion or pump is damaged, it will need to be serviced or replaced. Call Customer Care to obtain detailed instructions regarding servicing or replacement procedures.
- If your pump is accidentally submerged in water and the battery cap and infusion set hub are in place, you can towel dry the outside of the pump. Inspect the reservoir compartment and battery compartment and dry any water you find with a Q-tip. Do **NOT** use a hair dryer to dry your pump. If your pump was submerged in salt water, thoroughly clean with a damp cloth before drying.
- If your pump is accidentally submerged in water and the battery cap or the infusion set is **NOT** properly installed, submersion will likely damage internal pump components.
- If your companion is accidentally submerged in water, you can towel dry the outside of the companion. Do **NOT** recharge or reuse the companion. Contact Customer Care.

Daily Living:

In the left column of the following table, find the activity you are going to do. Then look in the right column for information and instructions about wearing your pump during that activity.

If the activity is	Do This
Normal Daytime Activity	Choose a convenient way to wear your pump. You can place the pump: • In the belt clip that came with the pump and clip the device onto your belt or waistband. • In a pocket. • Inside a bra or other item of clothing. • In a cloth pouch you can fasten around your waist, thigh, ankle, or other area. ***Caution:*** *If the pump is carried at a vertically higher position than the infusion site, a very small amount of additional insulin infusion may take place. To minimize this condition and maintain pump delivery accuracy, the pump should be carried* ***no higher than 12 inches (30 cm) above the insertion site****. For those using basal rates of less than 1.0 units per hour, this may be especially important. When using very low basal rates, position the pump vertically below the level of the infusion site to eliminate this condition.*
Sleeping	Choose where to place the pump according to your sleeping habits. **If you** / **Then** Do **NOT** want pump attached to your sleepwear — Place the pump next to you on your mattress. ***Note:*** *If you use tubing 42 inches or longer, you can put the pump on your nightstand.* Want pump attached to your sleepwear — Attach the pump to your sleepwear as you would for normal daytime activity (as above). ***Important Note:*** *Before you go to sleep, be sure the tubing is* ***NOT*** *where pets or children might pull or chew on it.*

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If the activity is	Do This
Bathing or Showering	***Caution:*** • *You should remove your pump before prolonged exposure to water, or temperatures above 104ºF (40º C) such as might occur with the use of a hot tub, sauna, or whirlpool.* • *If your pump is damaged, it will need to be serviced or replaced. Call Customer Care to obtain detailed instructions regarding servicing or replacement procedures.* **a.** Disconnect your pump tubing from the infusion site and remove it before bathing or showering. Keep your basal running; you do not need to stop your pump. **b.** Take your bath or shower. **c.** Reconnect to the pump. ***WARNING:*** • *When reconnecting, be sure to check that there is **NO** air in the tubing. If there is air in the tubing, you will **NOT** get the correct insulin dose. Follow your healthcare professional's recommendations on priming to replace any air in the tubing before reconnecting, by using the pump's **PRIME TUBING** feature.* ***Caution:*** • *Follow your healthcare professional's recommendations for checking your blood sugar when you have been off the pump. To prevent high glucose, follow your healthcare professional's recommendations for replacing missed basal and bolus insulin when you are disconnected from the pump.* You should **NOT** have to prime again after the disconnection at the infusion site.

If the activity is	Do This
Exercising or Playing Sports	Determine if the activity or sport is too rough or prolonged to wear your pump, for example, football or soccer games.

If activity is	Then do this
Too rough or prolonged to wear the pump	1. Disconnect and remove the pump. 2. While off the pump, follow recommendations from your healthcare professional. 3. When you are ready to reattach the pump, follow your healthcare professional's recommendations for replacing the insulin you missed.
OK for wearing the pump	Decide if you need to select a different basal program for exercising according to your healthcare professional's recommendations.

If	And	Then do this
You need to select a different basal program	You have **NOT** set up a Temporary or Exercise program	1. Follow the steps in **Section 7.6** to create a temporary basal rate, **OR** follow the steps in **Section 7.2** to **Create a New Basal Program**. 2. Follow the steps in **Section 7.3 Select a Basal Program** to select the Exercise program you just created.
	You have already set up the program	Follow the steps in **Section 7.3 Select a Basal Program**.
Do **NOT** need a different basal program	→	Do nothing.

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If the activity is	Do This
Swimming	**a.** Disconnect the pump and remove it from your body. **b.** Decide how long you will be off the pump.

If off the pump for	Then
1 hour or less	Follow the directions for **Bathing or Showering**.
More than 1 hour	While off the pump, you may need to take injections of insulin with a syringe or reconnect to bolus during your time away. It is important to get specific instructions from your healthcare professional. Use an alternate insulin therapy method according to recommendations from your healthcare professional.

Engaging in Sexual Activity

Note: *Removing your pump is optional. If you decide to remove your pump, follow these directions:*

a. Disconnect and remove the pump from the infusion site.

Reminder: *Follow your healthcare professional's instructions for how long you can be off the pump without any insulin replacement.*

b. Keep your pump running and remember to reconnect your pump when you finish the activity, before you fall asleep.

Note: *Stopping the pump could cause insulin to retract into the tubing, and problems with delivery.*

Receiving Medical Treatment or Care

Talk with your healthcare professional about whether or **NOT** you should use your pump during outpatient procedures, hospitalizations, surgeries, or emergency room visits.

WARNING: *Do **NOT** take your pump into a MRI, X-ray, CAT scan or ultrasound equipment procedure room. You **MUST** disconnect your pump and store it away from the machines. Do **NOT** bring the companion or pump into the procedure room at anytime.*

If the activity is	Do This
Traveling	Remember these key points when traveling with your companion and pump:

Topic	Key Points
Different Time Zone	Manually change your pump time and date to match the time zone you are in so your basal doses are delivered at the correct time. ***Note:*** *Time zone changes also affect your meal, snack schedule, and actual amount of insulin delivered in a day. When planning a trip that involves time zone changes you should talk with your healthcare professional about how to best handle this issue.*
Changes in Daily Routine and Sleep Patterns and/or Shift Work	Talk with your healthcare professional about how to best handle these changes.
Travel by Air	Before and after flights: • Turn RF Off/On (refer to **Section 6.9**). During flights: • Prevent dehydration by keeping bottled water with you and drinking frequently. • Carry snacks and treatment for a low blood glucose in case of delays. • Check your blood glucose level frequently according to your healthcare professional's instructions.
Other Important Considerations	• Have your healthcare professional supply you with a prescription for insulin and the name of a doctor in the area of your travels. • Always carry your daily kit of supplies that will help you prevent emergencies, and keep with you at all times. (see **Section 4.3 Carry a Daily Kit**). Be sure to bring extra pump-related supplies with you, **NOT** in checked luggage.

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4.2 Perform Daily Checks

Purpose

To make sure:

- Your infusion site is clean and secure.
- Your reservoir insulin level is adequate for the day.
- Your companion is fully operating without defects.

When

Perform this procedure at the beginning of each day, with your pump already started delivering insulin based on your basal and bolus programs.

Materials

- The pump and diabetes-care supplies needed for this procedure depend on what you discover as you perform your checks. See the instructions within each step for specific information.
- Your companion with battery charged and settings programmed.

Helpful Information

- These steps should become part of your daily routine to prevent problems.
- Refer to **Section 6.7** for instructions on performing a self test on your companion.

Procedure:

Steps	Do This
1. Examine your infusion site.	**a.** See that your infusion site is clean of any visible dirt. **b.** See that there are NO signs of infection or irritation.

If you notice	Then do this
Discomfort or tenderness Redness or inflammation Warmth, discharge or drainage	Change the infusion site and follow the instructions of your healthcare professional for treating the infection.
You have a temperature	Change your infusion set and contact your healthcare professional.
A firm lump under your skin at the catheter site	Change infusion set and contact your healthcare professional immediately.

WARNING: *Always check your blood glucose 1 to 3 hours after inserting a new infusion set or according to recommendations from your healthcare professional.*

Steps	Do This
2. Check your reservoir insulin level.	When considering how much insulin remains in your reservoir, be sure to think about what's going on in your life today that may affect how much insulin you may need: • What were the results from your blood glucose tests? • Are you planning on exercising? • What are you planning to eat? • Are you menstruating? • Are you sick? If you do **NOT** have adequate insulin in your reservoir, follow the procedure in **Section 2.3 Fill Reservoir**.
3. Look at all the tubing.	Make sure there are **NO** air bubbles in the tubing. Follow your healthcare professional's instructions if you see air bubbles.
4. Check your work.	You will begin your day having confirmed: • Your infusion site is clean and healthy. • Your tubing is free of air bubbles. • Your insulin reservoir has an ample supply of insulin to meet the demands of your day.

Important Note: *Check your blood glucose level as frequently as recommended by your healthcare professional and follow recommendations from your healthcare professional when your blood glucose is too high or too low.*

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4.3 Carry a Daily Kit

Purpose	To take care of your daily pump needs.
When	Do this procedure every day.
Materials	Keep a **daily kit** with you at ALL times. This kit should include: • Blood glucose monitoring supplies • Ketone monitoring supplies • Glucose tablets/gel or liquid or other source of carbohydrate to treat a low glucose condition. • A Glucagon Emergency Kit (Glucagon Emergency Kits have an expiration date). ***Important Reminder:*** *Check frequently to make sure your Glucagon Emergency Kit has* ***NOT*** *expired.* • Extra infusion sets • Insulin • Extra unopened pump reservoirs • An extra AAA alkaline battery • Dressings and adhesives • Spare battery cap • Insulin syringe and short or rapid-acting insulin vial or insulin pen. ***Important Reminder:*** *Insulin is sensitive to temperature extremes. Replace your spare insulin monthly.*

5 Testing Your Blood Glucose

5.1 Perform a Control Solution Test

Purpose	To check that the integrated **FreeStyle Lite Blood Glucose Meter** and **FreeStyle Lite Test Strips** are working properly without using any blood.
When	Do this procedure: • When you first get your **Aviator Companion**, before doing a blood glucose test with the integrated **FreeStyle Lite Blood Glucose Meter**. • Whenever you need to practice testing without having to use your own blood. • You want to confirm that your companion and test strips are working properly.
Materials	• **FreeStyle Lite Test Strips** • **FreeStyle Control Solution** • Your **Aviator Companion** fully operating

Helpful Information

The **FreeStyle Control Solution** is a red liquid that contains a fixed amount of glucose.

For information on how to obtain control solution, call Customer Care.

Important: FreeStyle Control Solution *is good for three months after opening the bottle or until the expiration date printed on the label, whichever comes first.*

Important: *Count forward three months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle.*

Example: *You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.*

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Ensure accurate control solution results by doing the following:

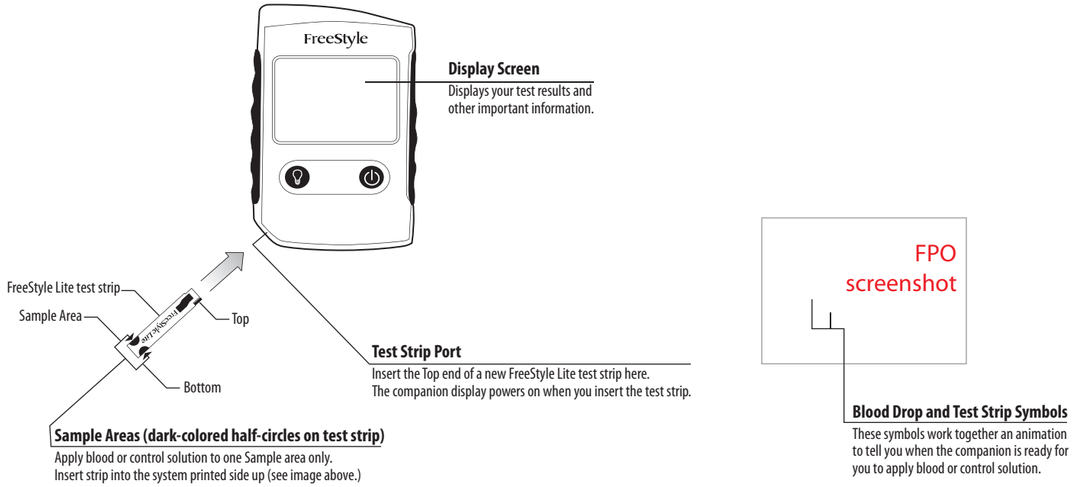
- Use **ONLY FreeStyle Control Solution** and **FreeStyle Lite Test Strips**.
- Replace the cap on the control solution bottle immediately after using.
- Do **NOT** use control solution after the expiration date.
- Do **NOT** add water or any liquid to control solution.
- Control solution tests are specified to be accurate **ONLY** when used between 59º to 104º F (15º to 40ºC).
- Control solution test results should fall within the appropriate range printed on the test strip vial label.

Important: *The control solution range is a target range for control solution only. It is **NOT** a target range for your blood glucose level.*

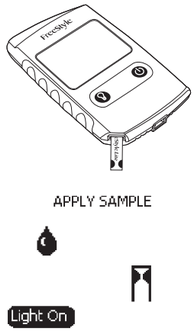
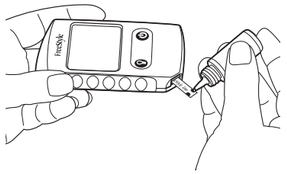
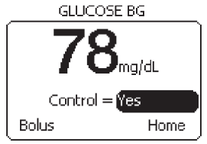
- If control solution results are out of this range, repeat the test.
- If your control solution test results continue to fall outside of the appropriate range printed on the test strip vial, do **NOT** use the integrated **FreeStyle Lite Blood Glucose Meter** to test your blood glucose. Contact Customer Care.

Caution: *Results from **FreeStyle Control Solution** tests do **NOT** reflect your blood glucose level.*

Important Note: *For important test strip information, including detailed storage and usage information, refer to the **FreeStyle Lite Test Strip** package insert.*



Procedure:

Steps	Do This
1. Insert test strip into the companion. 	***WARNING:*** *Do **NOT** insert any foreign materials in the meter's test strip port.* ***WARNING:*** *Remove USB cable before testing. If you insert a test strip into the strip port when the companion is plugged in, you will get the following warning: **BG Check not available**.* Insert the top of a **FreeStyle Lite Test Strip** into the test strip port until it stops, and the display switches on. ***Note:*** *If you do **NOT** start the test **within 2 minutes**, the meter will turn off. To restart your meter, take out the unused **FreeStyle Lite Test Strip** and reinsert it into the meter.* Wait for the screen to display the Blood Drop and Test Strip symbols.
2. Apply control solution to test strip. 	Gently squeeze the control solution vial so that a drop of control solution touches only ONE side of **the sample area** of the test strip to the control solution. ***Important:*** *Do **NOT** apply control solution to both test strip sample areas.* ***Note:*** *If the sound prompt is on, your companion will beep when the test strip is full. An image of a moving clock will appear while the sample is processing.*
3. Observe the results. 	**a.** Look at the results appearing on the display screen, and listen for 2 beeps if the sound is on. **b.** To mark the result as a control solution result, scroll to **Control** and press **Enter**. **c.** Change to **Yes** and press **Enter**. ***Note:*** *Result is marked as control solution when advanced to next screen.*

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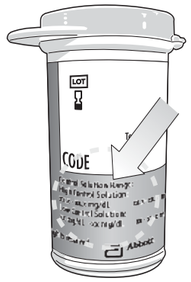
Steps	Do This
4. Compare Solution Range. 	**a.** Compare your control solution test result to the appropriate range printed on your test strip vial label. **b.** Check that your control solution results are within the appropriate range printed on your test strip vial. ***Note:*** *Out of range test results may be caused by:* • *Expired or bad control solution.* • *Expired or bad test strip.* • *Error in performing test, such as applying blood sample incorrectly, or using control solution that has expired.* • *Watered-down control solution.* • *Device malfunctions.* • *Control solution test done outside 59º to 104º F (15º to 40º C).* **c.** Remove the test strip.
5. Remove and discard the test strip.	Discard all used test strips as they are for single use only. Follow local regulations on safe disposal of used test strips.
6. Check your work.	You have obtained control solution results that fall within the appropriate range, as printed on your test strip vial.

5.2 Check Your Blood Glucose

Purpose	To obtain an accurate blood glucose reading using the integrated **FreeStyle Lite Blood Glucose Meter** on your **Aviator Companion**.
When	Do this procedure: • Whenever you need to check your blood glucose manually using the integrated **FreeStyle Lite Blood Glucose Meter** on your companion.
Materials	• Soap, water, and a clean towel • **FreeStyle Lite Test Strips** • A lancing device (**FreeStyle Lancing Device** or another brand) • Sterile lancets • A Sharps container • Your companion

Helpful Information

How the integrated **FreeStyle Lite Blood Glucose Meter** should be used:

- The integrated **FreeStyle Lite Blood Glucose Meter** is intended for use outside the body (in other words, *in vitro* diagnostic use only).
- The integrated **FreeStyle Lite Blood Glucose Meter** is used for measuring blood glucose (also known as blood sugar) from samples taken from the fore arm, upper arm, hand, thigh, calf, or fingers.

USE the integrated **FreeStyle Lite Blood Glucose Meter** for:

- Testing blood glucose.
- Testing only with fresh capillary whole blood samples (in vitro).

Do **NOT** use the integrated **FreeStyle Lite Blood Glucose Meter** for:

- The diagnosis of diabetes.
- Testing of newborns.
- Testing of arterial blood.

WARNING:

- *The **FreeStyle Lite** test strips and lancets are small parts that may be dangerous if swallowed.*
- *Peritoneal dialysis solutions containing icodextrin or compounds of Galactose ≥ 13 mg/dL (≥ 0.7 mmol/L), Maltose ≥ 20 mg/dL (≥0.6 mmol/L) or Lactose ≥ 10 mg/dL (≥ 0.3 mmol/L) cause the integrated **FreeStyle Lite Blood Glucose Meter** to overestimate blood glucose test results. If you are receiving such treatment, do **NOT** use the integrated **FreeStyle Lite Blood Glucose Meter** and discuss this issue with your healthcare professional to ensure proper alternative treatment.*

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Caution: *Please read all the instructions provided in this section and practice the testing procedures before using the integrated* ***FreeStyle Lite Blood Glucose Meter****. Blood glucose monitoring should be done with the guidance of a healthcare professional.*

Important health-related information:

- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
- Test results below 60 mg/dL (3.3 mmol/L) mean low blood glucose (**hypoglycemia**).
- Test results greater than 240 mg/dL (13.3 mmol/L) mean high blood glucose (hyperglycemia).
- If you get results below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L) and do **NOT** have symptoms of hypoglycemia or hyperglycemia, repeat the test. If you have symptoms or continue to get results that fall below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), follow the treatment of your healthcare professional.
- If you are experiencing symptoms that are **NOT** consistent with your blood glucose test and you have followed all instructions described in this section, call your healthcare professional.

Important: *To ensure accurate results, wash your hands and test site (for example, your forearm) with soap and water. Make sure there is* ***NO*** *cream or lotion on the test site. Thoroughly dry your hands and test site.*

- With the **Aviator Companion**, you can test your blood glucose on your forearm, fingers, upper arm, hand, thigh, or calf.
- Testing with the integrated **FreeStyle Lite Blood Glucose Meter** requires a very small sample size, 0.3 microliter of blood. This is about the size of a pinhead (example: •).

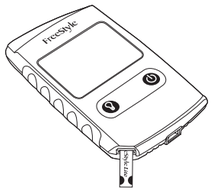
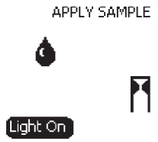
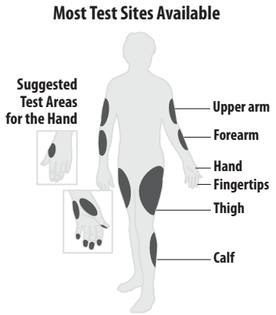
WARNING: *Test* ***ONLY*** *on fingers if you think blood glucose may be low, you have hypoglycemic unawareness, or your glucose is changing rapidly.*

Times when you may consider checking for low blood glucose include:

- When you are feeling symptoms such as weakness, sweating, nervousness, headache or confusion.
- When you have delayed a meal after taking insulin.
- When your healthcare professional advises you to do so.

Important: *Use* ***ONLY*** *the* ***FreeStyle Lite Test Strips*** *with the* ***Aviator Companion****. Using other test strips will produce inaccurate results.*

Procedure:

Steps	Do This
1. Prepare your companion.	Insert a **FreeStyle Lite Test Strip** into the strip port until it stops, and the display switches on. ***WARNING:*** *Remove USB cable before checking your BG. If you insert a test strip into the strip port when the companion is plugged in, you will get the following warning:* ***BG Check not available****.* ***Note:*** *If you do* ***NOT*** *start the test within 2 minutes, the display will turn off. To start the display, take out the unused* ***FreeStyle Lite Test Strip*** *and reinsert it into the strip port.*
	
	Check the screen to ensure that the blood drop and test strip symbols appear on the display screen. ***Note:*** *When you insert a test strip and the Apply Sample screen appears, you can turn on or off the display backlight and test light.*
2. Select a test site.	
	Select from among the test sites shown including the boxed areas. ***WARNING:*** *Test only on your fingers if you are testing for hypoglycemia (low blood glucose) or if you have hypoglycemia unawareness.* ***Note:*** *The areas shown can be tested with the integrated* ***FreeStyle Lite Blood Glucose Meter****. Avoid moles, veins, bones, and tendons.*

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Steps	Do This
3. Obtain a blood sample using your lancing device.	**a.** Wash your hands and the selected site with soap and water. Make sure there is no lotion or cream on the test site. **b.** Thoroughly dry your hands and the test site. ***Note:*** Refer to the ***FreeStyle Lancing Device*** insert for detailed instruction. If you are using another lancing device brand, follow the instructions that came with it. ***Important:*** Do ***NOT*** reuse lancets. Use a new sterile lancet for each test. ***NEVER*** use a lancet for more than one person. **c.** Prepare the test site for lancing. **d.** Use your lancing device to obtain the blood sample. ***Note:*** *It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another test site and/or change the depth setting.*

If you are using	Then do this
A finger	Gently massage the finger to bring blood to the surface.
Your forearm	Rub the test site vigorously until you feel it getting warm (three to five seconds).

Steps	Do This
4. Fill test strip with blood sample.	**a.** Make sure the FreeStyle Lite Test Strip is in the strip port and the display is switched on. Take out the test strip and reinsert it into the strip port if the display is off. ***Note:*** *The Blood Drop and Test Strip symbols should appear on the display screen.* **b.** Bring the test strip to the blood sample at a slight angle, and gently touch the half-circle on the test strip to the sample. ***Note:*** *The **FreeStyle Lite Test Strip** acts like a sponge and pulls the blood into the strip through the sample area.* ***Important:*** • *Do **NOT** use **FreeStyle Lite Test Strips** more than once. Discard used test strips.* • *Do **NOT** press the **FreeStyle Lite Test Strip** against the test site.* • *Do **NOT** scrape the blood onto the **FreeStyle Lite Test Strip**.* • *Do **NOT** apply blood to the flat side of the **FreeStyle Lite Test Strip**.* • *Do **NOT** apply blood to the **FreeStyle Lite Test Strip** when the test strip is out of the strip port.* • *Do **NOT** apply blood to both edges of the **FreeStyle Lite Test Strip**.* • *Do **NOT** put blood or foreign objects into the **FreeStyle Lite Test Strip** port.*

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Steps | Do This

5. Wait for result.

PROCESSING

GLUCOSE BG
78 mg/dL
Control = No
Bolus Home

a. Observe the companion screen.

Note: *Do **NOT** pull the **FreeStyle Lite Test Strip** away until you hear **ONE** beep or see the image of the clock moving on your companion screen. This means you have enough blood and the companion is reading your glucose.*

Note: *If after **5** seconds your companion screen does **NOT** show the image of a moving clock, the sample may be too small. You may add blood to the same sample area of the test strip with which you started for up to **60** seconds from the time of the first application.*

If	Then
The image of the clock moving does **NOT** appear after **5** seconds	Continue adding blood sample to the SAME half-circle.
The companion beeps once	Enough blood was applied.
Your blood glucose test results appear in the display (usually takes **5-7** seconds), and you hear two beeps	The test is complete, go to the next step.
The companion beeps three times	The test has failed. Repeat the test. Go to Step **12** to troubleshoot error messages.

b. The test result is complete when your blood glucose result is shown on the display screen and you hear two beeps.

Note: *On average, your results will display in **5** seconds. The time that the companion takes depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.*

Steps | Do This

6. Decide if the blood glucose reading is control solution.

GLUCOSE BG
78 mg/dL
Control = No
Bolus Home

If reading is	Then do this
Control	1. Use the scroll to select **Control**. 2. Press **Enter** button. 3. Scroll to select **Yes**. 4. Press **Enter** button.
Not control	Notice **Control = No** Go on to the next step.

7. Decide if a Bolus needs to be delivered.

GLUCOSE BG
78 mg/dL
Control = No
Bolus Home

a. Notice **Bolus** is highlighted.

b. Press the **Enter** button.

c. Notice the **Bolus** menu is displayed. Decide what type of bolus to deliver and refer to **Section 8** of this User's Guide to administer the bolus.

Note: *If a bolus is **NOT** needed, and you want to return to the **Home** screen, scroll to highlight **Home** and press **Enter** button.*

d. Go to the next step.

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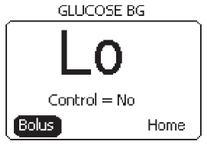
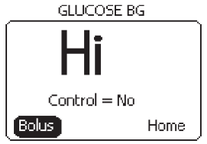
Steps | Do This

8. Interpret the blood glucose results.

***Important**: Low or high glucose readings can indicate a potentially serious medical condition.*

*The **Aviator Companion** can display results from 20 to 500 mg/dL (1.1 to 27.8 mmol/L).*





If	And	Then
Lo appears in the display -- test result is lower than 20 mg/dL (1.1 mmol/L)	You do **NOT** have low blood glucose symptoms	Repeat the test with a new test strip. Test on your finger.
	You have symptoms such as weakness, sweating, nervousness, headache or confusion	Follow your healthcare professional's recommendations for treating severe hypoglycemia (low blood glucose).
	This is your second test	
Hi appears in the display – test result is above 500 mg/dL (27.8 mmol/L)	You do **NOT** have high blood glucose symptoms	Repeat the test (rewashing your hands) using a new test strip.
	You have symptoms such as fatigue, thirst, excess urination or blurry vision	Follow your healthcare professional's recommendations for treating hyperglycemia (high blood glucose).
	This is your second test	
The companion displays results from 20 to 500 mg/dL (1.1 mmol/L to 27.8 mmol/L)		Continue to the next step.

9. Remove and discard the test strip.

Discard all used test strips as they are for single use only

Steps | Do This

10. Discard the lancet.

***Important:** Use a sealed container such as a sharps container to avoid exposure to the sharps by yourself or someone else. Your community may requires safe disposal of sharps. Follow local regulations.*

11. Check your work.

- ❑ You have obtained accurate blood glucose readings.
- ❑ Ensure you have followed all the steps and obtained an accurate BG reading.

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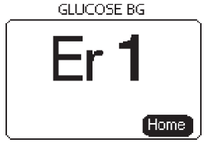
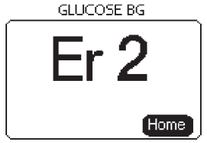
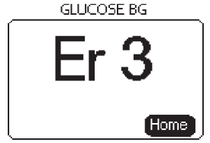
Steps	Do This
12. Troubleshooting Error Messages. 	**Error 1 (Er 1) Possible Causes:** • Sample is too small. • Problem with the **FreeStyle Lite Test Strip**. • Problem with the companion. • Very low blood glucose (less then 20 mg/dL [1.1 mmol/L]). **What You Should Do:** 1. If you have symptoms such as weakness, sweating, nervousness, headache or confusion, follow your healthcare professional's recommendation for treating hypoglycemia. 2. Conduct a control solution test using a new **FreeStyle Lite Test Strip**. If the results of the control solution test are within the appropriate range printed on the side of your test strip vial, retest using blood and a new **FreeStyle Lite Test Strip**. 3. If the retest using control solution does NOT work or the error persists, call Customer Care.
	**Error 2 (Er 2) Possible Causes:** • Problem with the **FreeStyle Lite Test Strip**. • Problem with the companion. • Very high blood glucose (above 500 mg/dL [27.8 mmol/L]). • HIGH control solution applied when temperature is too cold. (This applies only to control solution that is labeled as HIGH). **What You Should Do:** 1. If you have symptoms such as thirst, fatigue, excess urination or blurry vision, follow your healthcare professional's recommendation for treating hyperglycemia. 2. Conduct a control solution test using a new **FreeStyle Lite Test Strip**. If the results of the control solution test are within the appropriate range printed on your test strip vial, retest using blood and a new **FreeStyle Lite Test Strip**. 3. If the retest using control solution does **NOT** work or the error persists, call Customer Care.

Steps	Do This
Troubleshooting Error Messages (continued). 	**Error 3 (Er 3) Possible Causes:** • Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the strip port or applying blood before the blood drop and test strip symbols display. • Problem with the **FreeStyle Lite Test Strip**. • Problem with the companion. **What You Should Do**: 1. Be sure you see the blood drop and test strip symbols on the display screen before you apply blood or control solution. 2. Conduct a control solution test using a new FreeStyle Lite Test Strip. If the results of the control solution test are within the appropriate range printed on your test strip vial, retest using blood and a new FreeStyle Lite Test Strip. 3. If the retest using control solution does NOT work or the error persists, call Customer Care.
(Er 4 screenshot) FPO	**Error 4 (Er 4) Possible Causes:** • Problem with the **FreeStyle Lite Test Strip**. • Problem with the companion. **What You Should Do**: 1. Conduct a control solution test using a new **FreeStyle Lite Test Strip**. If the results of the control solution test are within the appropriate range printed on the side of your test strip vial, retest using blood and a new **FreeStyle Lite Test Strip**. 2. If the retest using control solution does **NOT** work or the error persists, call Customer Care.

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Steps	Do This

Troubleshooting Other Problems (continued).

1. **Companion does NOT enter the test mode after inserting a test strip.**

Probable Cause	What to Do
The battery is depleted	Recharge the battery (and reset the date and time, if necessary.)
Test strip inserted upside down, wrong-end in, or incompletely inserted into the companion	Insert the **FreeStyle Lite Test Strip** with the printed side up and the top of the strip in the strip port.
Defective companion or test strips	Call Customer Care.
Blood or foreign objects inserted into the test strip port.	Call Customer Care.

2. **Test does NOT start after applying the blood sample.**

Probable Cause	What to Do
Blood sample too small	You may add blood to the same sample area of the **FreeStyle Lite Test Strip** from which you started for up to 60 seconds from the time of the first application. If necessary, repeat the test using a new **FreeStyle Lite Test Strip** and a larger blood sample.
Defective test strip	Repeat the test with a new **FreeStyle Lite Test Strip**.
Sample applied after companion times out (two minutes) and turns off	Repeat the test using a new test strip. Wait until you see the blood and test strip symbols on the display screen before you apply the blood sample.
Defective companion or test strips	Call Customer Care.

6 When You're Ready – Optional Settings

6.1 Set Up Additional Options – SETUP WIZARD

Purpose

To program additional settings using your **Aviator Companion** following a step-by-step process in **SETUP WIZARD**, including:

- Display preferences
- Bolus calculator options
- Bolus and basal limits
- Audio/vibrate
- Low insulin alert and alarms
- Locked items
- One-button bolus

When

Do this procedure:

- After you have set up basic settings for your pump.
- After you have created a daily basal program.
- Whenever you are ready or need to set optional settings using **SETUP WIZARD**.

Materials

- Your companion with the battery charged and initial settings programmed
- Your pump with the battery installed and initial settings programmed.
- Your personalized Table of Settings recommended by your healthcare professional in **Section 12 - Appendix A**.

Helpful Information

- Your healthcare professional will need to help you determine your individual settings. Refer to **Section 12** for more information on why and how you would use these optional settings.
- Locking the basal, bolus, and prime options should be considered if a caregiver is responsible for operating the pump when the user is a child, elderly, or other person with a limited understanding of the pump use and functions.
- If you choose to turn the Magnify option to **On**, then in some cases, the full text does **NOT** fit on the screen, so it will require more scrolling to view the entire message. The behavior of each screen will vary, for example, when you are programming, only the option name will appear, and you will need to scroll further to view the option choices; in the basal or bolus calculator screens, you may see only the time block, and you will need to scroll further to get to the next programming choice.
- It is recommended that you practice using the Magnify **On** vs. Magnify **Off**, and scroll through the screens so you can become familiar with how the screen will appear using either option.

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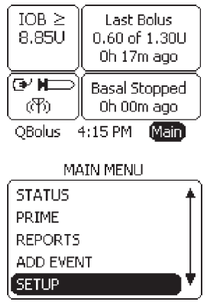
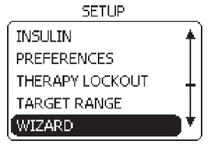
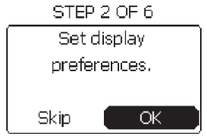
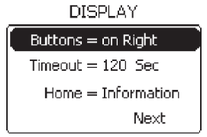
Helpful Information (continued)

- When' the **occlusion alarm** is set to high sensitivity, it will detect an occlusion and sound an alarm within the time it would take to deliver 3 Units of insulin at your programmed basal delivery rate, or within 1 minute, whichever is longer.
- When the occlusion alarm is set to low sensitivity, it will detect an occlusion and sound an alarm within the time it would take to deliver 6 Units of insulin at your programmed basal delivery rate, or within 2 minutes, whichever is longer.
- For a detailed list of the screen settings and the order in which they appear, refer to the **FreeStyle Aviator Menus** in **Section 12 – Appendix E.**

Procedure:

Steps	Do This
1. Go to the SETUP menu.  	**a.** **STOP** basal delivery before you go to the **SETUP** menu. See ***Section 3.1.3*** for procedure as needed. **b.** Notice **Main** is highlighted. **c.** Press **Enter** button. **d.** Scroll to highlight **SETUP**. **e.** Press **Enter** button.
2. Access SETUP WIZARD.  	**a.** Scroll to highlight **WIZARD**. **b.** Press **Enter** button.

Steps	Do This
3. Go to the STEP 2 screen  	**a.** On the **STEP 1** screen, notice **OK** is highlighted. ***Note:*** *You may have to scroll through several screens to get to the options that you want.* **b.** Scroll to highlight **Skip**. **c.** Press **Enter** button. **d.** Notice **Edit** is highlighted on the **CONFIRM** screen with "Skip or edit optional settings?" message. **e.** Press **Enter** button. **f.** On **STEP 2** screen, notice **OK** is highlighted. **g.** Press **Enter** button.
4. Set Display Preferences.  	**a.** Review the default settings and change as needed. ***Note:*** *Buttons on Right will allow controls to be on the right side of pump face. These do **NOT** affect button settings on the **Companion**.* **b.** Scroll to highlight **Buttons**. **c.** Press **Enter** button. **d.** Scroll to select display **on Right** or **on Left** of the screen. **e.** Press **Enter** button. **f.** If the settings are **NOT** correct, scroll up to the setting that needs to be changed, press **Enter**, change the value(s), and press **Enter** again. Review the changes. **g.** Scroll to highlight **Next**, if it is not already highlighted. **h.** Press **Enter** button.

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Steps	Do This
5. Set Timeout. DISPLAY Buttons = on Right Timeout = 120 Sec Home = Information Next	***Note:*** *The timeout is the number of seconds before the pump display goes blank. The timeout can be set from 15 to 120 seconds. You may want to set it at 30-60 seconds if you are frequently timing out while performing tasks.* **a.** Notice **Timeout** is highlighted. **b.** Press **Enter** button. **c.** Scroll to select timeout seconds ranging from 15 sec to 120 sec. **d.** Press **Enter** button.
6. Set Home screen display. DISPLAY Buttons = on Right Timeout = 120 Sec Home = Activity Next	**a.** Notice **Home** is highlighted. **b.** Press **Enter** button. **c.** Select **Information** (default) or **Activity display** for Home screen. **d.** Press **Enter** button. Example: **Information based** (displays basal and bolus insulin delivery status information) IOB 4.66U / Last Bolus 3.30 of 5.20U 0h 05m ago / Daily Basal 0.80 U/h / QBolus 3:48 PM Main **Activity based** (displays a list of menu items such as Alarms, Status, **Reports**, Setup, etc IOB 4.66U / STOP BASAL / BOLUS / BASAL / STATUS / ADD EVENT / QBolus 3:48 PM Main
7. Verify Display Preferences are correct. DISPLAY Buttons = on Right Timeout = 120 Sec Home = Activity Next	**a.** Scroll up to select and change any setting as needed. **b.** Notice **Next** is highlighted. **c.** Press **Enter** button. ***Note:*** *The **Home** screen examples in this User's Guide are set to **Information**.*

Steps	Do This
8. Select Edit Mode. EDIT MODE Cursor = Highlight Magnify = On Next EDIT MODE Cursor = Highlight Magnify = On Next	**a.** Review the default settings for how the screen shows your options or selections. **b.** Change as needed. ***Note:*** The screenshot examples in this User's Guide are set to ***Highlight*** and ***Magnify*** by default. **c.** Scroll to highlight **Cursor** for the option to highlight or outline text on the screen. **d.** Press **Enter** button. **e.** Scroll to select **Highlight** or **Outline**. **f.** Press **Enter** button.
Example of Cursor set to Outline: EDIT MODE Cursor = Outline Magnify = On Next EDIT MODE Cursor = Highlight Magnify = On Next	**g.** Notice **Magnify** is highlighted. This option allows text to be a larger font on the pump for easier reading. **h.** Press **Enter** button. **i.** Scroll to select **On** or **Off**. **j.** Press **Enter** button.
9. Verify Edit Mode is correct. EDIT MODE Cursor = Highlight Magnify = On Next	**a.** Scroll up to select and change any setting as needed. **b.** Notice **Next** is highlighted. **c.** Press **Enter** button.

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Steps	Do This
10. Set Bolus Calculator Options. STEP 3 OF 6 Set bolus calculator options. Skip OK	***Note:*** *The* ***Bolus Calculator*** *is a tool to allow you to easily determine how many units are needed for your bolus. It also shows you the numbers used to calculate that volume.* **a.** Notice **OK** is highlighted. **b.** Press **Enter** button.

Steps	Do This
11. Set 1U DROP (correction factor) for Block 1.	***WARNING: Accurate determination and programming of the insulin to blood glucose ratios are necessary to avoid possible delivery errors that may result in adverse medical events or serious injury.*** ***Note: 1U DROP*** *sets how much 1 unit of insulin will lower your blood glucose level.(Insulin Sensitivity Factor)* ***Note:*** *The 1U Drop can be changed to different values throughout a 24 hour period. The range is 12 AM to 11 PM in* ***1 hour increments****. Create your earliest block first. Once you add a block at 11 PM (the last time slot), you will* ***NO*** *longer see the* ***Add Block*** *option on the* ***1U Drop*** *screen and you* ***CANNOT*** *add any additional blocks. If you ONLY set* ***ONE*** *block, it* ***will prevail for 24 hours****.*
1U DROP Time mg/dL 00:00:00 ---- Add Block Next	**a.** Notice Time line and dashes are highlighted. **b.** Press **Enter** button. **c.** Notice **Time** is highlighted. **d.** Press **Enter** button. **e.** Scroll to the desired time.
BLOCK 1 Time = --:-- AM 1U Drop = -- mg/dL Next Delete	**f.** Press **Enter** button. **g.** Notice **1U Drop** is highlighted. **h.** Press **Enter** button.
BLOCK 1 Time = 12:00 AM 1U Drop = 50 mg/dL Next Delete	**i.** Scroll to the correction factor (insulin sensitivity factor) recommended by your healthcare professional and recorded in your Table of Settings in **Appendix A**. **j.** Press **Enter** button. ***Note:*** *The default is 50 mg/dL (2.8 mmol/L), and the range is 5 mg/dL to 500 mg/dL (0. 28 mmol/L - 27.8 mmol/L).*

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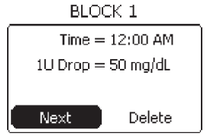
Steps / Do This

12. Check that the time and 1U Drop for the block are correct.



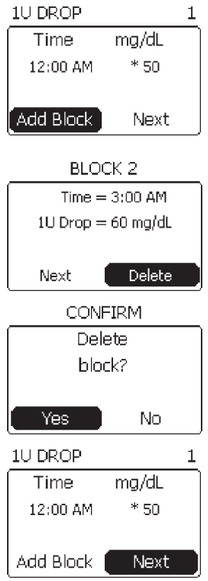
a. Review the **Time** and **1 U Drop** settings on the screen.

b. Scroll up to select and change any setting as needed.

c. Notice **Next** is highlighted.

d. Press **Enter** button.

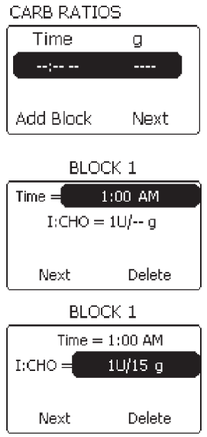
13. Decide whether to add another block, delete the block, or continue to set carb ratios.



If you want to	Then do this
Add another block	1. Notice **Add block** is highlighted. 2. Press **Enter** button 3. Repeat Steps 11 to 13 to add additional blocks per your healthcare professional's recommendations.
Delete the block	1. Scroll to highlight **Delete**. 2. Press **Enter** button. 3. Scroll to **Yes** to confirm block deletion. 4. Press **Enter** button.
Continue to set carb ratios	***Note:*** *You must add at least 1 block before continuing or you will get a warning. Clear the warning by pressing **Enter** button.* Scroll to highlight **Next** if not already highlighted. Press **Enter** button.

Steps / Do This

14. Set CARB RATIOS.



WARNING: *Accurate determination and programming of the insulin to carbohydrate ratios are necessary to avoid possible delivery errors that may result in adverse medical events or serious injury.*

a. Notice **Time** line and dashes are highlighted.

b. Press **Enter** button.

c. Notice **Time** is highlighted.

d. Press **Enter** button.

e. Scroll to the desired time.

f. Press **Enter** button.

g. Notice **I:CHO** is highlighted.

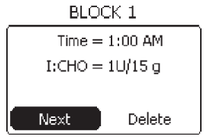
h. Press **Enter** button.

i. Scroll to select desired **I:CHO**.

Note: *This sets the amount of insulin for a certain number of **carbohydrates**. The default setting is 1U/15g and the range is 1U/1g to 1U/150g.*

Press **Enter** button.

15. Check that the time and I:CHO for the block are correct.



a. Review the **Time** and **I:CHO** settings on the screen.

b. Scroll up to select and change any setting as needed.

c. Notice **Next** is highlighted.

d. Press **Enter** button.

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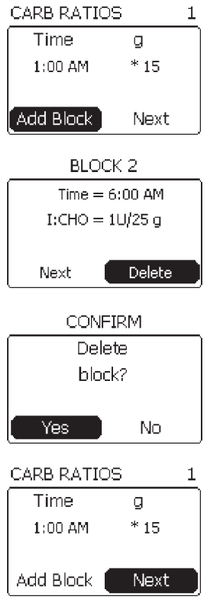
Steps | Do This

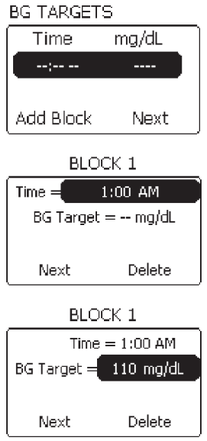
16. Decide whether to add another block, delete the block or continue to set BG targets.



If you want to	Then do this
Add another block	1. Notice **Add block** is highlighted. 2. Press **Enter** button. 3. Repeat Steps 14 to 16 to add additional blocks.
Delete the block	1. Scroll to highlight **Delete**. 2. Press **Enter** button. 3. Scroll to **Yes** to confirm block deletion. 4. Press **Enter** button.
Continue to set ***BG target***s	***Note:*** *You must add at least 1 block before continuing.* Scroll to highlight **Next** if not already highlighted. Press **Enter** button.

Steps | Do This

17. Set BG TARGETS.



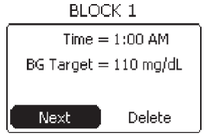
WARNING: *Accurate determination and programming of blood glucose targets is necessary to avoid possible delivery errors that may result in adverse medical events or serious injury.*

a. Notice **Time** line and dashes are highlighted.
b. Press **Enter** button.
c. Notice **Time** is highlighted.
d. Press **Enter** button.
e. Scroll to the desired time.
f. Press **Enter** button.
g. Notice **BG Target** is highlighted.
h. Press **Enter** button.
i. Scroll to the desired blood glucose target.

Note: *The default setting is 110 mg/dL (6.1 mmol/L), and the range is 50 mg/dL to 300 mg/dL (2.8 mmol/L to 16.7 mmol/L).*

j. Press **Enter** button.

18. Check that the time and BG Target settings are correct.



a. Review the **Time** and **BG Target** settings on the screen.
b. Scroll up to select and change any setting as needed.
c. Notice **Next** is highlighted.
d. Press **Enter** button

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Steps / Do This

19. Decide whether to add another block, delete the block or continue.

BG TARGETS 1
Time mg/dL
1:00 AM * 110
Add Block Next

BLOCK 2
Time = 11:00 PM
BG Target = 110 mg/dL
Next Delete

CONFIRM
Delete block?
Yes No

BG TARGETS 1
Time mg/dL
1:00 AM * 110
Add Block Next

If you want to	Then do this
Add another block	1. Notice **Add block** is highlighted. 2. Press **Enter** button. 3. Repeat Steps 17 to 19 to add additional blocks.
Delete the block	1. Scroll to highlight **Delete**. 2. Press **Enter** button. 3. Scroll to **Yes** to confirm block deletion. 4. Press **Enter** button.
Continue to set bolus and basal limits	***Note:*** *You must add at least 1 block before continuing.* Scroll to highlight **Next** if not already highlighted. Press **Enter** button to go to **STEP 4** screen, **Set bolus and basal limits**.

20. Set bolus and basal limits.

STEP 4 OF 6
Set bolus and basal limits.
Skip OK

a. Notice **OK** is highlighted.
b. Press **Enter** button to reach **BOLUS LIMITS** screen.

Steps / Do This

21. Set BOLUS LIMITS.

BOLUS LIMITS
Increment = 0.10 U
Maximum = 10.0 U
Next

a. Scroll to highlight bolus **Increment**.
b. Press **Enter** button.

Note: *Increment values are 0.05, 0.10, 0.50, or 1.00 Units. The default setting is 0.10U.*

c. Scroll to the desired increment.
d. Press **Enter** button.

Note: *If you changed the increment in step **c**, you **MUST** also reset the **Maximum** bolus.*

BOLUS LIMITS
Increment = 0.10 U
Maximum = 10.0 U
Next

e. Notice **Maximum** is highlighted.
f. Press **Enter** button.

Note: *The scrolling range depends on the increment you selected above. See the following table:*

If increment is	Then range is
0.05 U	0.05 to 9.95 U
0.10 U	0.10 to 50.0 U
0.50 U	0.50 to 50.0 U
1.00 U	1.00 to 50.0 U

g. Scroll to select desired maximum units of insulin.
h. Press **Enter** button.

22. Check that the Increment and Maximum values are correct.

BOLUS LIMITS
Increment = 0.10 U
Maximum = 10.0 U
Next

a. Review the **Increment** and **Maximum** settings on the screen.
b. Scroll up to select and change any settings as needed.
c. Notice **Next** is highlighted.
d. Press **Enter** button.

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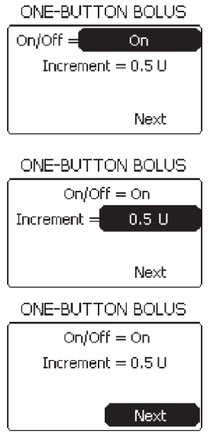
Steps / Do This

23. Set ONE-BUTTON BOLUS.



a. Scroll to highlight **On/Off**. The default is **On**.

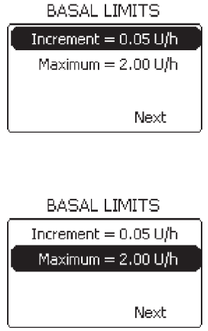
b. Press **Enter** button.

c. Scroll to select **On** or **Off**.

d. Press **Enter** button.

If	Then do this
On	1. Notice **Increment** is highlighted. 2. Press **Enter** button. 3. Scroll to select desired increment. (**0.5U** or **1.0U**). 4. Press **Enter** button. 5. Notice **Next** is highlighted. 6. Press **Enter** button.
Off	Notice **Next** is highlighted and **Increment** is gone from the screen. Press **Enter** button.

24. Set BASAL LIMITS.



a. Scroll to highlight **Increment**.

b. Press **Enter** button.

Note: *Increment values are 0.05, 0.10, 0.50, and 1.00 U/h. The default setting is 0.05 U/h.*

c. Scroll to select desired increment.

d. Press **Enter** button.

e. Notice **Maximum** is highlighted.

f. Press **Enter** button.

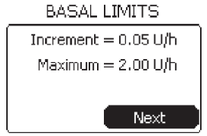
Note: *This sets the maximum limit for basal rates when you edit your basal programs. The default is 2.00 U/h, and the range is 0.05-30.00 U/h.*

g. Scroll to select desired maximum U/h.

h. Press **Enter** button.

Steps / Do This

25. Check that the basal limit increments and maximums are correct.



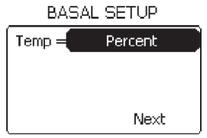
a. Review **Increment** and **Maximum** settings on the screen.

b. Scroll up to select and change any setting as needed.

c. Notice **Next** is highlighted.

d. Press **Enter** button.

26. Set Temporary Basal setting.



a. Notice **Temp** is highlighted.

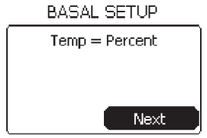
b. Press **Enter** button.

c. Scroll to select **Percent** or **Units**.

Example: If your active basal rate is 0.35 U/h, then selecting 75% will set the temporary basal at 0.26 U/h, which is 75% of the current basal.

d. Press **Enter** button.

27. Check that the Temp Basal setting is correct.



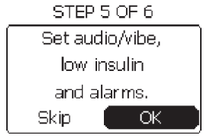
a. Review your **Temp** setting on the screen.

b. Scroll up to select and change any setting as needed.

c. Notice **Next** is highlighted.

d. Press **Enter** button.

28. Set audio/vibe, low insulin, and alarms.



If you want to	Then do this
Set audio or vibe, low insulin, and alarms	1. Notice **OK** is highlighted. 2. Press **Enter** button. 3. Go to Step 29.
Skip this set up	1. Scroll to highlight **Skip**. 2. Press **Enter** button. 3. Go to Step 35 to set locked items.

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Steps | Do This

29. Set AUDIO/VIBRATE.

AUDIO/VIBRATE
Pump = Audio
Audio = High
Next

AUDIO/VIBRATE
Pump = Audio
Audio = High
Next

AUDIO/VIBRATE
Pump = Audio
Audio = High
Next

Note: *The **Audio/Vibrate** setting establishes whether your pump will notify you with audible sounds or vibrations.*

a. Notice **Next** is highlighted.

b. Scroll to highlight **Pump**.

c. Press **Enter** button.

d. Scroll to select **Audio** (default) or **Vibrate**.

e. Press **Enter** button.

If you select	Then do this
Audio	Notice **Audio** is highlighted. Press **Enter** button. Scroll to select **Low**, **Medium**, or **High**. Press **Enter** button.

30. Verify AUDIO/VIBE setting.

AUDIO/VIBRATE
Pump = Audio
Audio = High
Next

Review your **Pump** setting on the screen.

If setting is	Then do this
Correct	Notice **Next** is highlighted. Press **Enter** button.
Incorrect	Repeat Step 29.

Steps | Do This

31. Set OCCLUSION ALARM.

OCCLUSION ALARM
Sensitivity = High
Next

OCCLUSION ALARM
Sensitivity = High
Next

Note: *The **Occlusion Alarm** alerts you that there is pressure in your pump or tubing sensed the pump. This can result in insulin **NOT** being delivered to your infusion site as programmed. The Occlusion Alarm Sensitivity is set to **High** by default.*

a. Notice **Next** is highlighted.

b. Scroll to highlight **Sensitivity**.

c. Press **Enter** button.

d. Scroll to select **High** or **Low**.

e. Press **Enter** button.

32. Check that OCCLUSION ALARM sensitivity is correct.

OCCLUSION ALARM
Sensitivity = High
Next

Notice your **Sensitivity** setting on the screen.

If setting is	Then do this
Correct	Notice **Next** is highlighted. Press **Enter** button.
Incorrect	Repeat Step 31.

33. Set LOW INSULIN ALERT.

LOW INSULIN ALERT
Low Alert = 20 U
Next

LOW INSULIN ALERT
Low Alert = 5 U
Next

a. Notice **Next** is highlighted.

b. Scroll to highlight **Low Alert** (Number of units left in reservoir when pump alarms).

c. Press **Enter** button.

d. Scroll to set low insulin **alert** level.

e. Press **Enter** button.

Note: *The default is 20U. The range is 5U to 50U.*

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Steps	Do This
34. Verify LOW INSULIN ALERT level is correct LOW INSULIN ALERT Low Alert = 5 U Next	**a.** Review your **Low Alert** setting on the screen. **b.** Scroll up to select and change the level as needed. **c.** Notice **Next** is highlighted. **d.** Press **Enter** button.
35. Set LOCKED ITEMS. STEP 6 OF 6 Set locked items. Skip OK	**a.** Notice **OK** is highlighted on the screen **STEP 6 Set locked items** (Used in the case that the patient needs to be prevented from changing settings or giving insulin). **b.** Press **Enter** button.
36. Set Basal to Locked or Unlocked. LOCKED ITEMS Basal = Unlocked Bolus = Unlocked Prime = Unlocked Next LOCKED ITEMS Basal = Unlocked Bolus = Unlocked Prime = Unlocked Next	**a.** Review locked items settings, and change as needed. **b.** Scroll to highlight **Basal**. **c.** Press **Enter** button. **d.** Scroll to select **Locked** or **Unlocked**. **e.** Press **Enter** button.

Steps	Do This
37. Set Bolus to Locked or Unlocked. LOCKED ITEMS Basal = Unlocked Bolus = Unlocked Prime = Unlocked Next	**a.** Notice **Bolus** is highlighted or scroll to highlight **Bolus** as needed. **b.** Press **Enter** button. **c.** Scroll to select **Locked** or **Unlocked**. **d.** Press **Enter** button.
38. Set Prime to Locked or Unlocked. LOCKED ITEMS Basal = Unlocked Bolus = Unlocked Prime = Locked Next	**a.** Notice **Prime** is highlighted or scroll to highlight **Prime** as needed. **b.** Press **Enter** button. **c.** Scroll to select **Locked** or **Unlocked**. **d.** Press **Enter** button.
39. Verify your LOCKED ITEMS settings. LOCKED ITEMS Basal = Unlocked Bolus = Unlocked Prime = Locked Next	**a.** Review the Locked **Basal**, **Bolus**, and **Prime** settings on the screen. **b.** Scroll up to select and change any settings as needed. **c.** Notice **Next** is highlighted. **d.** Press **Enter** button
40. Check your work. SETUP WIZARD Setup Wizard is complete. Done	**a.** You will see the message "**Setup Wizard is complete**." on the **SETUP WIZARD** screen. ***Note:*** *The screen will automatically go to the* ***Home*** *screen after 5 seconds.* **b.** To check your settings, follow the sequence in this task to proceed through each screen. **c.** **RESTART** YOUR BASAL DELIVERY.

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6.2 Edit Additional Options

Purpose

To edit additional options using your **Aviator Companion** following direct menu options or the **SETUP WIZARD** including:

- **audio/vibe settings**
- inactivity or occlusion alarms
- low insulin alert
- time/date format
- basal and bolus limits
- one-button bolus setting
- display settings
- blood glucose target range
- system name
- locked items
- insulin profile
- **bolus calculator** options

Note: *Refer to the* ***Glossary*** *for explanation of the above terms.*

When

Do this procedure:

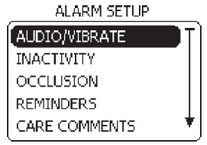
- Whenever you want to make changes to your **current** pump settings.

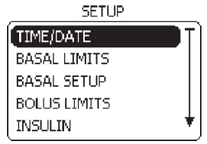
Materials

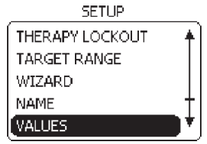
- Your companion fully operating with initial and optional settings programmed.
- Your pump fully operating with initial and optional settings programmed.
- Your healthcare professional's recommendations for the settings of your pump.
- Your personalized Table of Settings in **Appendix A**.

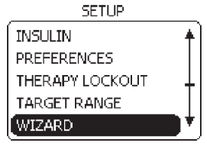
Procedure:

Steps	Do This
1. Determine what settings you want to edit.	









If you are editing	Then do this
Audio or vibrate settings	Make your edits from the **ALARMS** menu. Go to Step **2**.
Inactivity alarm	
Occlusion alarm	
Low Insulin alert	
Time or date format	Make your edits from the **SETUP** menu Go to Step **7**.
Basal limits	
Basal Setup (Temporary basal setup)	
Bolus limits/One-button bolus setting	
Insulin Profile	
Preferences/ Display settings	
Name of system	
BG Target Range	
Values	You **CANNOT** change the default insulin type and unit values. ***Note: Aviator Pump*** *uses U100 insulin only.*
More than **3 SETUP WIZARD** settings (including bolus calculator options, locked items, etc.)	Make your edits from the **SETUP WIZARD** menu. Refer to **Section 6.1: Set Additional Options** for the procedure to change all the desired settings.

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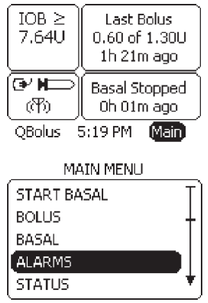
Steps / Do This

2. Access the ALARMS menu.



a. From the **Home** screen, notice **Main** is highlighted.

b. Press **Enter** button.

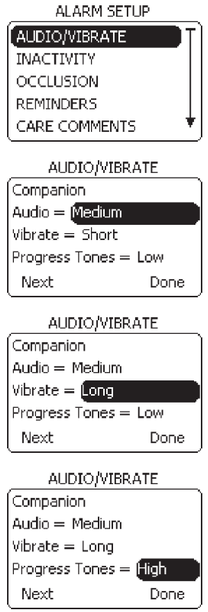
c. Scroll to highlight **ALARMS**.

d. Press **Enter** button to display the **ALARMS** menu.

e. Decide which alarm you want to edit.

If you are editing	Then do this
Audio or vibrate settings	Go to Step **3**.
Inactivity alarm	Go to Step **4**.
Occlusion alarm	Go to Step **5**.
Low Insulin alert	Go to Step **6**.

3. Edit AUDIO/VIBRATE.



a. Notice **Audio/Vibrate** is highlighted.

b. Press **Enter** button.

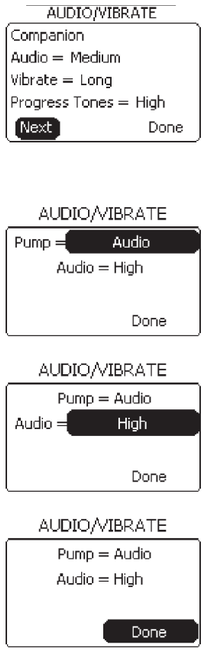
c. Scroll to highlight **Audio**, **Vibrate**, or **Progress Tones** to change as needed for the companion.

d. Press **Enter** button.

e. Scroll to select values as recommended by your healthcare professional.

f. Press **Enter** button.

Continued on next page.



g. Notice **Next** is highlighted.

h. Press **Enter** button.

i. Decide to select **Audio** or **Vibrate** for the Aviator Pump.

If you want your pump to be on	Then do this
Audio and at a different level	1. Scroll to highlight **Audio**. 2. Press **Enter** button. 3. Scroll to select **Low**, **Medium**, or **High**. 4. Press **Enter** button. 5. Notice **Done** is highlighted. 6. Press **Enter** button.
Vibrate	1. Scroll to highlight **Pump**. 2. Press **Enter** button. 3. Scroll to select **Vibrate**. 4. Press **Enter** button. 5. Notice **Done** is highlighted. 6. Press **Enter** button.

You have completed editing the Audio/Vibrate setting.

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Steps	Do This
4. Edit INACTIVITY ALARM.	
ALARM SETUP AUDIO/VIBRATE INACTIVITY OCCLUSION REMINDERS CARE COMMENTS	**a.** Scroll to highlight **INACTIVITY**. **b.** Press **Enter** button.
INACTIVITY ALARM Time = 3 h Done	**c.** Scroll to highlight **Time**. **d.** Press **Enter** button. **e.** Scroll to set the time for the inactivity alarm to sound. ***Note:*** *Scrolling range is 1 - 24 hours.*
INACTIVITY ALARM Time = 3 h Done	**f.** Press **Enter** button. **g.** Notice **Done** is highlighted. **h.** Press **Enter** button. **You have completed editing the Inactivity Alarm setting.**
5. Edit OCCLUSION ALARM.	
ALARM SETUP AUDIO/VIBRATE INACTIVITY OCCLUSION REMINDERS CARE COMMENTS	**a.** Scroll to highlight **OCCLUSION**. **b.** Press **Enter** button. **c.** Scroll to highlight **Sensitivity**. **d.** Press **Enter** button. **e.** Scroll to select **High** or **Low**.
OCCLUSION ALARM Sensitivity = High Done	***Note:*** *Occlusion Alarm Sensitivity is set to* ***High*** *by default.* **f.** Press **Enter** button. **g.** Notice **Done** is highlighted.
OCCLUSION ALARM Sensitivity = High Done	**h.** Press **Enter** button. **You have completed editing the Occlusion Alarm setting.**

Steps	Do This
6. Edit LOW INSULIN ALERT.	
ALARM SETUP OCCLUSION REMINDERS CARE COMMENTS LOW INSULIN DONE	**a.** Scroll to highlight **LOW INSULIN**. **b.** Press **Enter** button.
LOW INSULIN ALERT Low Alert = 5 U Done	**c.** Scroll to highlight **Low Alert**. **d.** Press **Enter** button.
LOW INSULIN ALERT Low Alert = 5 U Done	**e.** Scroll to set low insulin level alert. ***Note:*** *Scrolling range is 5 - 50 U.* **f.** Press **Enter** button.
ALARM SETUP OCCLUSION REMINDERS CARE COMMENTS LOW INSULIN DONE	**g.** Notice **DONE** is highlighted. **h.** Press **Enter** button to return to Home screen. **You have completed editing the Low Insulin Alarm setting.**

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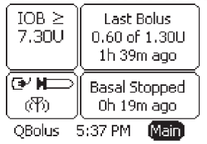
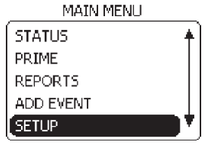
Steps | Do This

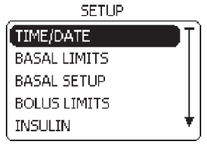
7. Go to the SETUP menu.

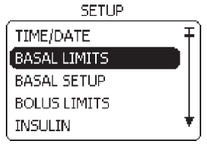


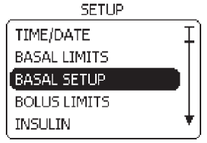


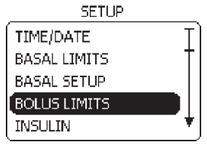
a. From the Home screen, Notice **Main** is highlighted.

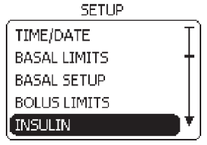
b. Press **Enter** button.











c. Scroll to highlight **SETUP**.

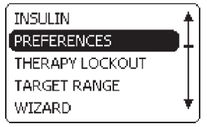
d. Press **Enter** button to go to **SETUP** menu.

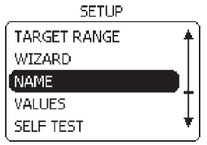
e. Decide which setting you want to edit.

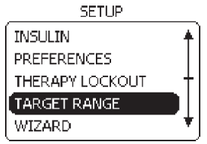
If you are editing	Then do this
Time and date format	1. Notice **TIME/DATE** is highlighted. 2. Press **Enter** button. 3. Go to Step 8 & 9.
Basal limits	1. Scroll to highlight **BASAL LIMITS**. 2. Press **Enter** button. 3. Go to Step 10.
Basal setup (Temporary basal setup)	1. Scroll to highlight **BASAL SETUP**. 2. Press **Enter** button. 3. Go to Step 11.
Bolus limits / One-Button Bolus	1. Scroll to highlight **BOLUS LIMITS**. 2. Press **Enter** button. 3. Go to Step 12.
Insulin Profile	1. Scroll to highlight **INSULIN**. 2. Press **Enter** button. 3. Go to Step 13.

Continued on next page.

Steps | Do This

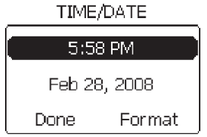






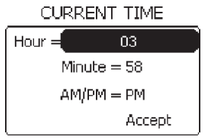
If you are editing	Then do this
Preferences/ Display Settings	1. Scroll to highlight **PREFERENCES**. 2. Press **Enter** button. 3. Go to Step 14.
Name of system	1. Scroll to highlight **NAME**. 2. Press **Enter** button. 3. Go to Step 15.
BG Target Range	1. Scroll to highlight **TARGET RANGE**. 2. Press **Enter** button. 3. Go to Step 16

8. Edit Time.



a. Scroll up to select the time.

b. Press **Enter** button.

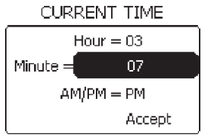


c. Scroll up to select **Hour**.

d. Press **Enter** button.

e. Scroll to set the current hour.

f. Press **Enter** button.



g. Notice **Minute** is highlighted.

h. Press **Enter** button.

i. Scroll to select the current minute.

j. Press **Enter** button.

Continued on next page.

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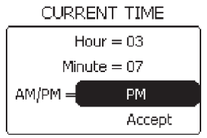
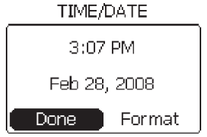
Steps | Do This





k. Notice **Am/Pm** is highlighted.

l. Press **Enter** button.

m. Scroll to select **AM** or **PM**.

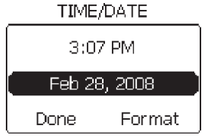
n. Press **Enter** button.

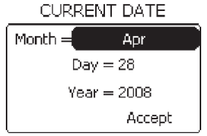
o. Notice **Accept** is highlighted.

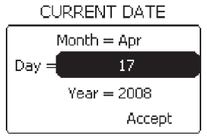
p. Press **Enter** button.

If you are changing	Then do this
Only the **time** and **NOT** the date	1. Scroll to highlight **Done**. 2. Press **Enter** button to return to **HOME screen**. **You have completed editing the time**.
The **date**	Go to Step 8.

9. Edit Date.







a. Notice the date is highlighted.

b. Press **Enter** button.

c. Scroll up to highlight **Month**.

d. Press **Enter** button.

e. Scroll to change month.

f. Press **Enter** button.

g. Notice **Day** is highlighted.

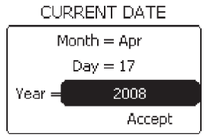
h. Press **Enter** button.

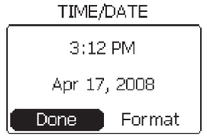
i. Scroll to change the day.

j. Press **Enter** button.

Continued on next page.

Steps | Do This





k. Notice **Year** is highlighted.

l. Press **Enter** button.

m. Scroll to change to current year as needed.

n. Press **Enter** button.

o. Notice **Accept** is highlighted.

p. Press **Enter** button.

q. Review date and time, and make changes as needed.

r. Notice **DONE** is highlighted.

s. Press **Enter** button to return to the **HOME screen**.

You have completed editing the date.

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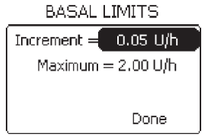
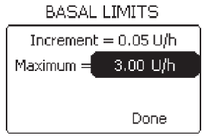
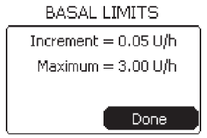
Steps | Do This

10. Edit Basal Limits.



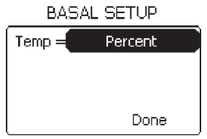


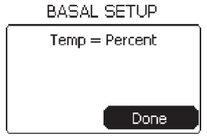


a. **STOP BASAL DELIVERY** to edit basal limits. See **Section 3.1.3** for procedure as needed.
b. Scroll up to highlight **Increment**.
c. Press **Enter** button.
d. Scroll to select desired increment.
e. Press **Enter** button.
f. Notice **Maximum** is highlighted.
g. Press **Enter** button.
h. Scroll to select desired maximum.
i. Press **Enter** button.
j. Review settings, and make changes as needed.
k. Notice **Done** is highlighted
l. Press **Enter** to return to the **Home screen**.
m. **RESTART BASAL DELIVERY** if you have no other edits.

You have completed editing the basal limits.

11. Edit Temp Basal Setup.



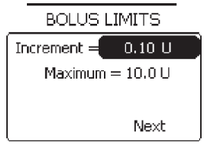


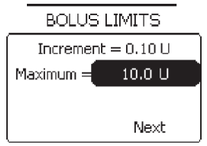
a. Scroll to highlight **Temp**.
b. Press **Enter** button.
c. Scroll to select **Percent** or **Units**.
d. Press **Enter** button.
e. Notice **Done** is highlighted.
f. Press **Enter** button to return to the **Home screen**.

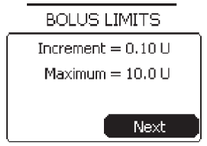
You have completed editing the temp basal setup.

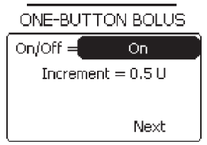
Steps | Do This

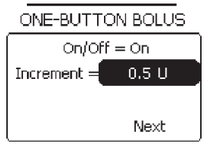
12. Edit Bolus Limits.

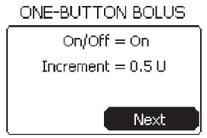












a. Scroll up to highlight **Increment**.
b. Press **Enter** button.
c. Scroll to select desired increment.
d. Press **Enter** button.
e. Notice **Maximum** is highlighted.
f. Press **Enter** button.
g. Scroll to select desired maximum.
h. Press **Enter** button.
i. Review settings. Notice **Next** is highlighted.
j. Press **Enter** button.
k. Notice **ONE-BUTTON BOLUS** screen displays.
l. Scroll up to highlight **On/Off**.
m. Press **Enter** button.
n. Scroll to select **On** or **Off**.
o. Press **Enter** button.

If you selected	Then do this
On	1. Notice **Increment** is highlighted. 2. Press **Enter** button. 3. Scroll to select desired increment. (**0.5 u** or **1.0 u**). 4. Press **Enter** button. 5. Review settings, and make changes as needed. 6. Notice **Done** is highlighted. 7. Press **Enter** button to return to the **Home screen**.
Off	Notice **Done** is highlighted and **Increment** is gone from the screen. Press **Enter** button to return to the **Home screen**.

You have completed editing the bolus limits.

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Steps	Do This
13. Edit Insulin Profile.	**a.** Scroll to highlight **Type**. **b.** Press **Enter** button. **c.** Scroll to select **Rapid** or **Short**. **d.** Press **Enter** button. **e.** Scroll to highlight **Action Time**. **f.** Scroll to select action time. **g.** Press **Enter** button. **h.** Notice **Next** is highlighted. **i.** Press **Enter** button to return to Home screen. You have completed editing the insulin profile.
14. Edit Display Preferences.	**a.** Notice **Timeout** is highlighted. **b.** Press **Enter** button. **c.** Scroll to select screen timeout ranging from 15 to 120 seconds. ***Note:*** *You may want to change your timeout to 30 or 60 seconds if you frequently timeout.* **d.** Press **Enter** button. **e.** Scroll to highlight **Cursor**. **f.** Press **Enter** button. **g.** Scroll to select **Highlight** or **Outline** (see examples on next page). **h.** Press **Enter** button. **i.** Scroll to highlight **Home**. **j.** Press **Enter** button. **k.** Select **Information** or **Activity** display for Home screen. **l.** Press **Enter** button. Continued on the next page.

Steps	Do This
	m. Scroll to highlight **Contrast**. **n.** Press **Enter** button. **o.** Scroll to select **0**, **1**, or **2 (Low, Medium, or High)**. **p.** Press **Enter** button. **q.** Review settings. **r.** Scroll to highlight **Done**. **s.** Press **Enter** button to return to **Home screen**. **You have completed editing the display preferences.**
15. Create/Edit Name to personalize your system.	***Note:*** *The name will display when you wake up the pump.* ***Reminder:*** *To get here from **Home** screen, go to **Main** menu, **Setup** menu and select **Name.*** **a.** Scroll to **highlight and select** each letter by pressing the **Enter** button to spell out the name you want for your system, for example, Amy. **b.** Scroll to highlight Done when you have finished spelling the name. **c.** Press Enter button to return to the Home screen. **You have completed creating/editing the name**.

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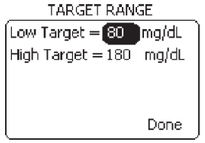
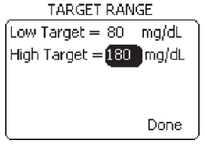
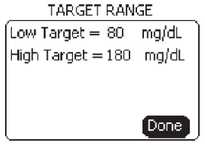
Steps	Do This
16. Edit BG Target Range.	
	**a.** Notice **Low Target** is highlighted. **b.** Press **Enter** button. **c.** Scroll to select desired low target value. **d.** Press **Enter** button.
	**e.** Scroll to highlight **High Target**. **f.** Press **Enter** button. **g.** Scroll to select desired high target value. **h.** Press **Enter** button.
	**i.** **Done** is highlighted. **j.** Press **Enter** button to return to the Home screen. **You have completed editing the BG target range**.
17. Check your work.	Repeat from Step 1 to review the different settings in the various menus. **RESTART YOUR BASAL DELIVERY** as needed.

6.3 Set Reminders and Care Comments

Purpose	To set **reminders** to alert you to a diabetes care task or to turn on certain **care comments** noted in your **Aviator Companion**.
When	Do this procedure: • When you need to set up a task reminder. • When you wish to set up care comments in your companion/pump.
Materials	• Your companion operating with all settings programmed. • Your pump operating with all settings programmed and delivering basal. • Assistance from healthcare professional as needed.

Helpful Information

- Reminders and Care Comments are set to **Off** by default, and are a choice to discuss with your healthcare professional.
- Reminders prompt you to perform certain tasks by making your pump beep or vibrate. They also display a screen message on the time or day that you specify.
- Up to six separate reminders can be programmed on your companion in any way or combination you choose from the list below (i.e., set six Check BG reminders, or two Check BG reminders and one Exercise reminder, or one snack reminder only if that's all you want.

Reminder Message	Time to
Check BG	Test your blood glucose
Meds	Take your medications
Snack	Eat a snack
Pickup	Do a pickup
Meeting	Attend a meeting
Exercise	Go for your exercise
Bolus	Deliver a bolus
Basal	Start or stop basal
Wakeup	Wake up from naps/sleep

- All reminders prompt you by making your pump beep or vibrate and display a screen message at the time you've specified, except for the **Bolus reminder**. If you deliver a bolus **within 2 hours** before the pump is scheduled to give you a reminder, it will **self-cancel** and you will **NOT** get that particular bolus reminder until the **next day**. These are non-recurring reminders.

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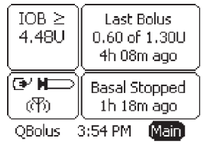
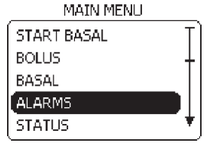
Procedure:

Steps	Do This

1. Go to the ALARMS menu.





a. From the **Home** screen, notice **Main** is highlighted.

b. Press **Enter** button.

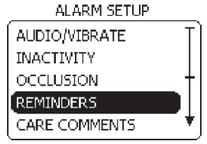
c. Scroll to highlight **ALARMS**.

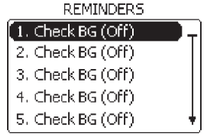
d. Press **Enter** button to go to **ALARMS** menu.

e. Decide which alarm you want to edit.

If you are setting	Then do this
Reminders	Go to Step **2**.
Care Comments	Go to Step **5**.

2. Set REMINDERS.





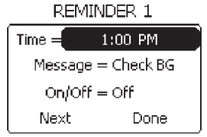
a. Scroll to highlight **REMINDERS**.

b. Press **Enter** button.

c. Notice **1. Check Bg (Off)** is highlighted.

d. Press **Enter** button.

3. Set time for REMINDERS.



a. Scroll to highlight **Time**.

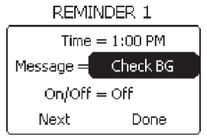
b. Press **Enter** button.

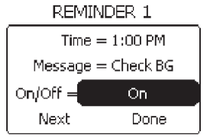
c. Scroll to set time for the first reminder.

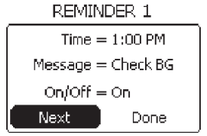
d. Press **Enter** button.

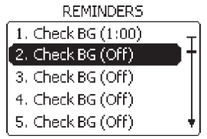
Steps	Do This

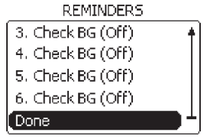
4. Set REMINDER Options.











a. Notice **Message** is highlighted.

b. Press **Enter** button.

c. Scroll to select **Check BG**, **Wakeup**, **Basal**, **Bolus**, **Exercise**, **Meeting**, **Pickup**, **Snack**, or **Meds**.

d. Press **Enter** button.

e. Notice **On**/**Off** is highlighted.

f. Press **Enter** button.

g. Scroll to select **On** or **Off**.

h. Press **Enter** button.

i. Decide what to do next.

If you want to	Then do this
Add reminders	1. Notice **Next** is highlighted. 2. Press **Enter** button to return to **REMINDERS** screen. 3. Scroll to highlight **2**. **Check BG (Off)**. 4. Press **Enter** button. 5. Repeat Steps 3 and 4 to add more reminders (up to six).
Finish setting up reminders	Scroll to highlight **Done**. Press **Enter** button to return to the **Home screen**.

You have completed setting up a reminder(s).

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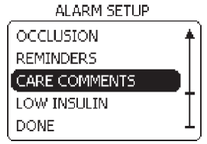
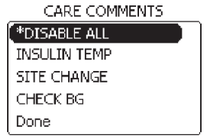
Steps | Do This

5. Set CARE COMMENTS.



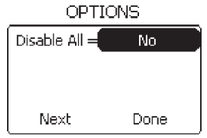
a. Scroll to highlight **CARE COMMENTS**.

b. Press **Enter** button.



c. Notice **Disable All** is highlighted.

> ***Note: Disable All** is set to **Yes** by default; all other options are initially off. The asterisk next to an item indicates the option is enabled. **Disable All** with **Yes** selected overrides settings for other care comments.*



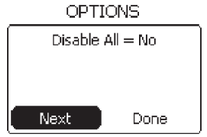
d. Press **Enter** button.

e. Scroll to highlight **Disable All**.

f. Press **Enter** button.

g. Scroll to select **No**.

h. Press **Enter** button.

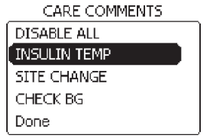


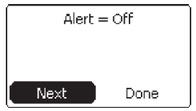
i. Notice **Next** is highlighted.

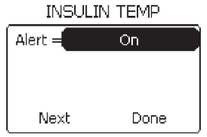
j. Press **Enter** button to return to **CARE COMMENTS** screen.

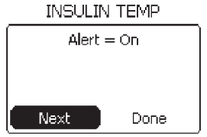
Steps | Do This

6. Set INSULIN TEMP, SITE CHANGE and/or CHECK BG.









Decide what care comments you want to set.

If you selected	Then do this
Insulin Temperature	1. Scroll to highlight **INSULIN TEMP**. ***Note:** The alarm will sound if the pump senses a temperature above or below the recommended insulin temperatures.* 2. Press **Enter** button. 3. Notice **Next** is highlighted. 4. Scroll to highlight **Alert**. 5. Press **Enter** button. 6. Scroll to select **On**. 7. Press **Enter** button. 8. Notice **Next** is highlighted (to set another care comment) **OR** scroll to highlight **Done**. 9. Press **Enter** button to return to **CARE COMMENTS** screen. **You have completed setting care comments for Insulin Temperature.**

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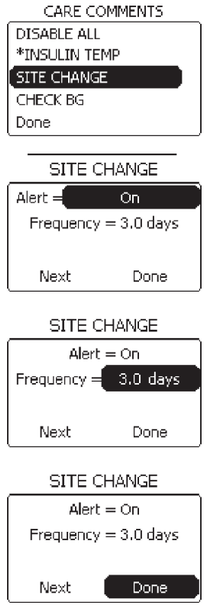
Steps

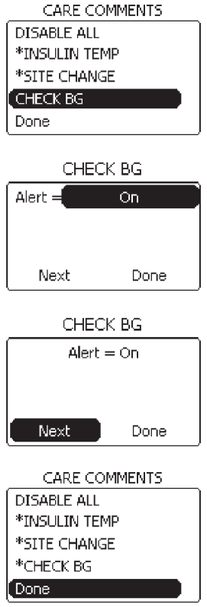


Do This

If you selected	Then do this
Site Change (to remind you to change your infusion set and site)	1. Scroll to highlight **SITE CHANGE**. 2. Press Enter button. 3. Notice Next is highlighted. 4. Scroll to highlight Alert. 5. Press Enter button. 6. Scroll to select On. 7. Press Enter button. 8. Notice Frequency is highlighted (default 2.0 days). 9. Press Enter button. 10. Scroll to set frequency. 11. Press Enter button. 12. Notice Next is highlighted (to set another care comment) OR scroll to highlight Done. 13. Press Enter button to return to the Home screen. **You have completed setting care comments for Site Change**.

Continued on next page.

Steps



Do This

If you selected	Then do this
Check BG (to remind you to test your blood glucose)	14. Scroll to highlight **CHECK BG**. 15. Press **Enter** button. 16. Notice **Next** is highlighted. 17. Scroll to highlight **Alert**. 18. Press **Enter** button. 19. Scroll to select **On**. 20. Press **Enter** button. 21. Notice **Next** is highlighted (to set another care comment) **OR** scroll to highlight **Done**. 22. Press **Enter** button to return to **CARE COMMENTS** screen. 23. Notice **Done** is highlighted. 24. Press **Enter** button to return to the **Home screen**. **You have completed setting care comments for Checking BG**.

7. **Check your work.**	To check your settings, follow the steps in this task from the beginning again to review each menu and screen.

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